

## ARTICLE 120 SELF-DECLARATION

### EU MDD DECLARATION OF CONFORMITY GLOBAL ADDENDUM FOR EXTENDED TRANSITION TO MDR

|                                                                     |                                                                                                                                                                                                                                                                                                                                                                                           |
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| <b>Legal Manufacturer (LM)</b>                                      | <p><u>Name:</u><br/>Teleflex Medical Sdn. Bhd</p> <p><u>Address:</u><br/>Lot PT 2577, Jalan Perusahaan 4,<br/>34600 Kamunting,<br/>Perak, Malaysia</p> <p><u>Contact:</u><br/>Davender Pal Singh<br/>Quality Director<br/><a href="mailto:Davenderpal.singh@teleflex.com">Davenderpal.singh@teleflex.com</a><br/>+605-8295111</p> <p><u>SRN:</u><br/>MY-MF-000024692</p>                  |
| <b>Authorized Representative</b>                                    | <p><u>Name:</u><br/>Teleflex Medical</p> <p><u>Address:</u><br/>IDA Business and Technology Park<br/>Dublin Road, Athlone,<br/>Co. Westmeath, Ireland</p> <p><u>Contact:</u><br/>Ida Foley<br/>Director of Regulatory Affairs – EMEA<br/><a href="mailto:ida.foley@teleflex.com">ida.foley@teleflex.com</a><br/>+353 (0)906 460881 ext. 500881</p> <p><u>SRN:</u><br/>IE-AR-000015869</p> |
| <b>Incoming Notified Body (MDR NB)</b>                              | <p><u>Name:</u><br/>DEKRA Certification GmbH</p> <p><u>Identification Number:</u><br/>0124</p>                                                                                                                                                                                                                                                                                            |
| <b>Notified Body That Issued the Certificate Under MDD (MDD NB)</b> | <p><u>Name:</u><br/>DEKRA Certification GmbH</p> <p><u>Identification Number:</u><br/>0124</p>                                                                                                                                                                                                                                                                                            |

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Teleflex Medical Sdn. Bhd declares that the product(s) listed in Appendix A meet the provisions of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices.

This declaration is made on the basis that the product(s) listed in Appendix A are currently compliant to:

- ☒ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of 120(3c), and are intended to or have been confirmed to meet the provisions of Regulation (EU) 2017/745 (MDR).
- ☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), the provisions of Article 120(3c), Article 120(2) points (a) or (b) of MDR, and are intended to meet the provisions of Regulation (EU) 2017/745 (MDR).
- ☐ Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD), and Article 120(3c) of MDR.

Furthermore, Teleflex Medical Sdn. Bhd declares:

- ☒ A formal application has been lodged in accordance with Section 4.3, first subparagraph, of Annex VII MDR before MDD certificate expiration or before 26 May 2024. The LM and MDR NB have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR before 26 September 2024.
- ☐ A Quality Management System (QMS) will be implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR) prior to 26 May 2024.
- ☐ A Quality Management System (QMS) has been implemented in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR), but is not yet certified.
- ☒ A Quality Management System (QMS) has been certified in compliance with Article 10(9) of Regulation (EU) 2017/745 (MDR).
- ☒ Post-market surveillance, market surveillance, vigilance, and economic operator requirements will be conducted pursuant to Article 120(3e) of the Regulation (EU) 2017/745 (MDR).
- ☒ The extended transitional period for the product(s) listed in Appendix A shall end on the dates stated in Appendix A, as set forth in Article 120(3) of the MDR.
- ☒ The product(s) listed in Appendix A will continue to comply with Council Directive 93/42/EEC dated 14 June 1993, as amended by 2007/47/EC (MDD); will not undergo any significant changes to the design or intended purpose; and do not present and unacceptable risk to health or safety of patients, users, or other persons or to other aspects of the protection of public health.

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#### Approvals

|                                             |                                                                                                                                                   |
|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Company Name:                               | Teleflex Medical Sdn. Bhd                                                                                                                         |
| Name, Title, and Email Address of Approver: | Angela Bouse<br>Senior Regulatory Affairs Manager<br><a href="mailto:angela.bouse@teleflex.com">angela.bouse@teleflex.com</a>                     |
| Signature of Approver:                      |                                                                  |
| Date Approved:                              | 01 May 2024                                                                                                                                       |
| Place of Issue:                             | Teleflex Medical Sdn. Bhd<br>Lot PT 2577, Jalan Perusahaan 4,<br>34600 Kamunting,<br>Perak, Malaysia                                              |
| Company Name:                               | Teleflex Medical Sdn. Bhd                                                                                                                         |
| Name, Title, and Email Address of Approver: | Mohd Hayazi Bin Wan Chik<br>Senior Quality System Manager<br><a href="mailto:MohdHayazi.WanChik@teleflex.com">MohdHayazi.WanChik@teleflex.com</a> |
| Signature of Approver:                      |                                                                  |
| Date Approved:                              | 30 Apr 2024                                                                                                                                       |
| Place of Issue:                             | Teleflex Medical Sdn. Bhd<br>Lot PT 2577, Jalan Perusahaan 4,<br>34600 Kamunting,<br>Perak, Malaysia                                              |

#### Change History for Declaration of Conformity Addendum:

| Revision | Date      | Change Order Number or N/A | Reason for Revision |
|----------|-----------|----------------------------|---------------------|
| 00       | See Agile | DCO-076917                 | Initial release     |

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## APPENDIX A

Table 1: Nasopharyngeal Airway products

| Product Name                                           | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                                                    | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Nasopharyngeal Airway                                  | XRG125410              | 125410-000120<br>125410-000140<br>125410-000160<br>125410-000180<br>125410-000190<br>125410-000200<br>125410-000220<br>125410-000240<br>125410-000260<br>125410-000280<br>125410-000300<br>125410-000320<br>125410-000340<br>125410-000360 | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 18 July 2021                  | A21051006                                       |
| Wirupren® Nasopharyngeal Airway, Robertazzi pattern    | XRG185410              | 185410-000200<br>185410-000220<br>185410-000240<br>185410-000260<br>185410-000280<br>185410-000300<br>185410-000320<br>185410-000340<br>185410-000360                                                                                      | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 18 July 2021                  | A21051006                                       |
| Wirupren® Nasopharyngeal Airway with Adjustable Flange | XRG185420              | 185420-000120<br>185420-000140<br>185420-000160<br>185420-000180<br>185420-000200<br>185420-000220<br>185420-000240<br>185420-000260<br>185420-000280                                                                                      | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 18 July 2021                  | A21051006                                       |

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| Product Name | Product Code (MY code) | Product Code (SAP code)                                          | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------|------------------------|------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
|              |                        | 185420-000300<br>185420-000320<br>185420-000340<br>185420-000360 |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |

Table 2: Endotracheal Tube Stylet products

| Product Name                                                          | Product Code (MY code)       | Product Code (SAP code)                         | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-----------------------------------------------------------------------|------------------------------|-------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Slick <sup>®</sup> Stylet Disposable Endotracheal Stylet              | XRI500<br>XRI750<br>XRI1000R | 500<br>750<br>1000R                             | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 28 April 2023                 | A23031167                                       |
| RUSCH Flexislip Endotracheal Tube Stylet with Soft Distal Tip         | XRG503700                    | 503700-000100<br>503700-000120<br>503700-000140 | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 28 April 2023                 | A23031167                                       |
| Flexi-Slip <sup>™</sup> Endotracheal Tube Stylet with Soft Distal Tip | XRI5025                      | 502503<br>502505<br>502507                      | 50076-17-07              | 26 May 2024                       | 31 Dec 2028                             | Is                | Rule 5         | Annex IX                           | N/A                                | 28 April 2023                 | A23031167                                       |

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**Table 3: Endotracheal Tube products**

| Product Name                                                       | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                                                                                                       | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| RUSCHELIT®<br>Preformed Oral Tracheal Tube, Two Eyes without Cuff  | XRG100180              | 100180-000030<br>100180-000035<br>100180-000040<br>100180-000045<br>100180-000050<br>100180-000055<br>100180-000060<br>100180-000065<br>100180-000070                                                                                                                                         | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT®<br>Preformed Nasal Tracheal Tube, Two Eyes without Cuff | XRG100181              | 100181-000030<br>100181-000035<br>100181-000040<br>100181-000045<br>100181-000050<br>100181-000055<br>100181-000060<br>100181-000065                                                                                                                                                          | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT®<br>Safety Clear Tracheal Tube, oral/nasal               | XRG100380              | 100380-000020<br>100380-000025<br>100380-000030<br>100380-000035<br>100380-000040<br>100380-000045<br>100380-000050<br>100380-000055<br>100380-000060<br>100380-000065<br>100380-000070<br>100380-000075<br>100380-000080<br>100380-000085<br>100380-000090<br>100380-000095<br>100380-000100 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                                                | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                  | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|---------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| RUSCHELIT® Safety Clear Tracheal Tube, oral/nasal                                           | XRG100382              | 100382-000020<br>100382-000025<br>100382-000030<br>100382-000035<br>100382-000040<br>100382-000045<br>100382-000050<br>100382-000055<br>100382-000060<br>100382-000065<br>100382-000070<br>100382-000075 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Curved Reinforced Endotracheal Tube, oral/nasal, Murphy Eye, High Volume, Low Pressure Cuff | XRW103902              | 103902035<br>103902040<br>103902045<br>103902050<br>103902055<br>103902060<br>103902065<br>103902070<br>103902075<br>103902080<br>103902085<br>103902090<br>103902095<br>103902100                       | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff                                      | XRG104201              | 104201-000035<br>104201-000040<br>104201-000045<br>104201-000050<br>104201-000055<br>104201-000060<br>104201-000065<br>104201-000070                                                                     | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                                           | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                                                    | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
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|                                                                                        |                        | 104201-000075<br>104201-000080<br>104201-000085<br>104201-000090<br>104201-000095<br>104201-000100                                                                                                                                         |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff, Murphy Eye                     | XRG104202              | 104202-000035<br>104202-000040<br>104202-000045<br>104202-000050<br>104202-000055<br>104202-000060<br>104202-000065<br>104202-000070<br>104202-000075<br>104202-000080<br>104202-000085<br>104202-000090<br>104202-000095<br>104202-000100 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff and FlexiSlip Intubation Stylet | XRG104203              | 104203-000035<br>104203-000040<br>104203-000045<br>104203-000050<br>104203-000055<br>104203-000060<br>104203-000065<br>104203-000070<br>104203-000075<br>104203-000080<br>104203-000085<br>104203-000090<br>104203-000095<br>104203-000100 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                                                       | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                  | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| RuschFlex Armoured Tracheal Tube, oral/nasal with Cuff and FlexiSlip Intubation Stylet, Murphy Eye | XRG104204              | 104204-000050<br>104204-000055<br>104204-000060<br>104204-000065<br>104204-000070<br>104204-000075<br>104204-000080<br>104204-000085<br>104204-000090                                                    | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Preformed Oral Tracheal Tube, Cuffed, Oral, Murphy Eye                                  | XRG111780              | 111780-000035<br>111780-000040<br>111780-000045<br>111780-000050<br>111780-000055<br>111780-000060<br>111780-000065<br>111780-000070<br>111780-000075<br>111780-000080<br>111780-000085<br>111780-000090 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Preformed Nasal Tracheal Tube, Cuffed, Nasal, Murphy Eye                                | XRG111781              | 111781-000035<br>111781-000040<br>111781-000045<br>111781-000050<br>111781-000055<br>111781-000060<br>111781-000065<br>111781-000070<br>111781-000075<br>111781-000080                                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Nasal Safety Silk Tracheal Tube, nasal, with Cuff,                                      | XRG111782              | 111782-000030<br>111782-000035<br>111782-000040<br>111782-000045                                                                                                                                         | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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|-----------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Preformed, Murphy Eye                                           |                        | 111782-000050<br>111782-000055<br>111782-000060<br>111782-000065<br>111782-000070<br>111782-000075<br>111782-000080                                                                                      |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| RUSCHELIT® Safety Clear Plus Tracheal Tube, oral/nasal, Cuffed  | XRG112082              | 112082-000050<br>112082-000055<br>112082-000060<br>112082-000065<br>112082-000070<br>112082-000075<br>112082-000080<br>112082-000085<br>112082-000090<br>112082-000095<br>112082-000100                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Super Safety Clear Microlaryngeal Tube, oral/nasal   | XRG112460              | 112460-000040<br>112460-000050<br>112460-000060                                                                                                                                                          | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Super Safety Clear Tracheal Tube, oral/nasal, Cuffed | XRG112480              | 112480-000025<br>112480-000030<br>112480-000035<br>112480-000040<br>112480-000045<br>112480-000050<br>112480-000055<br>112480-000060<br>112480-000065<br>112480-000070<br>112480-000075<br>112480-000080 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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|                                                                                   |                        | 112480-000085<br>112480-000090<br>112480-000095<br>112480-000100                                                                                                                                                                                                             |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Flexiset Super Safety Clear Tracheal Tube, oral/nasal with Cuff and Insertion Aid | XRG112481              | 112481-000050<br>112481-000055<br>112481-000060<br>112481-000065<br>112481-000070<br>112481-000075<br>112481-000080<br>112481-000085<br>112481-000090                                                                                                                        | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| RUSCHELIT® Super Safety Clear Tracheal Tube, oral/nasal, Cuffed                   | XRG112482              | 112482-000025<br>112482-000030<br>112482-000035<br>112482-000040<br>112482-000045<br>112482-000050<br>112482-000055<br>112482-000060<br>112482-000065<br>112482-000070<br>112482-000075<br>112482-000080<br>112482-000085<br>112482-000090<br>112482-000095<br>112482-000100 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Super Safety Silk Tracheal Tube                                                   | XRG112680              | 112680-000050<br>112680-000055<br>112680-000060<br>112680-000065<br>112680-000070<br>112680-000075                                                                                                                                                                           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                    | Product Code (MY code) | Product Code (SAP code)                                                                                                                                                                                                                                     | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-----------------------------------------------------------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
|                                                                 |                        | 112680-000080<br>112680-000085<br>112680-000090<br>112680-000095<br>112680-000100                                                                                                                                                                           |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Super Safety Silk Tracheal Tube, Murphy eye                     | XRG112682              | 112682-000030<br>112682-000035<br>112682-000040<br>112682-000045<br>112682-000050<br>112682-000055<br>112682-000060<br>112682-000065<br>112682-000070<br>112682-000075<br>112682-000080<br>112682-000085<br>112682-000090<br>112682-000095<br>112682-000100 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Flexi-Set Cuffed Endotracheal Tube and Stylet Set, oral/nasal   | XRI5045                | 504550<br>504555<br>504560<br>504565<br>504570<br>504575<br>504580<br>504585<br>504590                                                                                                                                                                      | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Flexi-Set Uncuffed Endotracheal Tube and Stylet Set, oral/nasal | XRI5065                | 506525<br>506530<br>506535<br>506540<br>506545<br>506550                                                                                                                                                                                                    | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                  | Product Code (MY code) | Product Code (SAP code)                                                                                                                                  | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|---------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Preformed AGT Oral Endotracheal Tube uncuffed/plain - Murphy  | XRI100180              | 100180030<br>100180035<br>100180040<br>100180045<br>100180050<br>100180055<br>100180060<br>100180065<br>100180070                                        | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Preformed AGT Nasal Endotracheal Tube uncuffed/plain - Murphy | XRI100181              | 100181030<br>100181035<br>100181040<br>100181045<br>100181050<br>100181055<br>100181060<br>100181065                                                     | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Endotracheal Tube oral/nasal uncuffed/plain - Magill          | XRI100380              | 100380020<br>100380025<br>100380030<br>100380035<br>100380040<br>100380045<br>100380050<br>100380055<br>100380060<br>100380065<br>100380070<br>100380075 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Endotracheal Tube oral/nasal uncuffed/plain - Murphy          | XRI100382              | 100382020<br>100382025<br>100382030<br>100382035<br>100382040<br>100382045                                                                               | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                                     | Product Code (MY code) | Product Code (SAP code)                                                                                                                                  | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------------------------------------------------------------------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
|                                                                                  |                        | 100382050<br>100382055<br>100382060<br>100382065<br>100382070<br>100382075                                                                               |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Preformed AGT Oral Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff  | XRI111780              | 111780035<br>111780040<br>111780045<br>111780050<br>111780055<br>111780060<br>111780065<br>111780070<br>111780075<br>111780080<br>111780085<br>111780090 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Preformed AGT Nasal Endotracheal Tube Murphy Eye, High Volume, Low Pressure Cuff | XRI111781              | 111781035<br>111781040<br>111781045<br>111781050<br>111781055<br>111781060<br>111781065<br>111781070<br>111781075<br>111781080                           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |
| Endotracheal Tube oral/nasal Murphy Eye, High Volume, Low Pressure Cuff          | XRI112082              | 112082050<br>112082055<br>112082060<br>112082065<br>112082070<br>112082075<br>112082080                                                                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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| Product Name                                                        | Product Code (MY code) | Product Code (SAP code)                                       | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|---------------------------------------------------------------------|------------------------|---------------------------------------------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
|                                                                     |                        | 112082085<br>112082090<br>112082095<br>112082100              |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| RUSCHELIT ®<br>Safety Clear<br>Tracheal Tube,<br>oral/nasal, Magill | XRI112480              | 112480025<br>112480030<br>112480035<br>112480040<br>112480045 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 5         | Annex IX                           | N/A                                | 30 Jun 2023                   | A23031167                                       |

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**Table 4: Heat and Moisture Exchanger (HME) products**

| Product Name                  | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Humid-Vent Mini        | XKC10011               | 10011                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKC10012               | 10012                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Micro + 3.0 | XKC10121               | 10121                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Micro + 3.5 | XKC10131               | 10131                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent 1           | XKC11111               | 11111                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKC11112               | 11112                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent 1 Port      | XKC11132               | 11132                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent 2 Port      | XKC13311               | 13311                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKI13312               | 13312                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKC13312EU             | 13312EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent 2 S         | XKC14411               | 14411                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKI14412               | 14412                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Trach-Vent             | XKC41111               | 41111                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                               | XKC41112               | 41112                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Trach-Vent T           | XKC41131               | 41131                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                              | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Trach-Vent+                        | XKC41311               | 41311                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                           | XKC41311U              | 41311U                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Trach-Vent+                        | XKC41312               | 41312                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                           | XKC41312U              | 41312U                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Trach-Vent+ with Tube              | XKC41322               | 41322                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Hygroscopic Condenser Humidifier AQUA+ TS | XKC41574               | 41574                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Oxy Vent with Tube                 | XKC45512               | 45512                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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**Table 5: Catheter Mount products**

| Product Name                       | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate (s) No | MDD EC Certificate (s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|------------------------------------|------------------------|-------------------------|---------------------------|------------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Flex Tube                          | XKC20011               | 20011                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Expandi-Flex, Catheter Mount       | XKC22362               | 22362                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Smooth-Flo Flex with Double Swivel | XKC22511               | 22511                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                    | XKC22512               | 22512                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Expandi-Flex with Double Swivel    | XKC22531               | 22531                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                    | XKC22532               | 22532                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Expandi-Flex with Elbow            | XKC22542               | 22542                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Smooth-Flo Flex                    | XKC22552               | 22552                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Expandi-Flex                       | XKC22562               | 22562                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Swivel Connector                   | XKC23411               | 23411                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                    | XKC23412               | 23412                   | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount               | XKD191009S             | 191009-000050           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                    |                        | 191009-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                                    |                        | 191009-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name         | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate (s) No | MDD EC Certificate (s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------|------------------------|-------------------------|---------------------------|------------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| RUSCH Catheter Mount | XKD191011S             | 191011-000050           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191011-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191011-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191011-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191014              | 191014-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191014-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191014-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKC191014T             | 191014-T00150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191015S             | 191015-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191015-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191015-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191015ST            | 191015-T00150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191018              | 191018-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191019S             | 191019-000050           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191019-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191019-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name         | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate (s) No | MDD EC Certificate (s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------|------------------------|-------------------------|---------------------------|------------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
|                      |                        | 191019-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191020              | 191020-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191020-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191020-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191021S             | 191021-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191021-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191021-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKC191024              | 191024-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191024-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191025S             | 191025-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191033S             | 191033-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191034              | 191034-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191036              | 191036-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191037S             | 191037-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name         | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate (s) No | MDD EC Certificate (s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------|------------------------|-------------------------|---------------------------|------------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| RUSCH Catheter Mount | XKD191040              | 191040-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191045S             | 191045-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191081S             | 191081-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191525              | 191525-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191526S             | 191526-000000           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| RUSCH Catheter Mount | XKD191653S             | 191653-000050           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191653-000100           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191653-000150           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
|                      |                        | 191653-000200           | 50076-16-08               | 26 May 2024                        | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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**Table 6: Bacterial Viral Filter Products**

| Product Name                                 | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Iso-Gard Filter A                     | XKC18211               | 18211                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter A                     | XKC18212               | 18212                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter A, Tethered Cap       | XKC18211T              | 18211T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter Small A               | XKC18511               | 18511                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S                     | XKC19211               | 19211                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S                     | XKC19212               | 19212                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S, Tethered Cap       | XKC19211T              | 19211T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S, Tethered Cap       | XKC19212T              | 19212T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter Small S               | XKC19511               | 19511                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter Small S               | XKC19512               | 19512                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter Small S, Tethered Cap | XKC19511T              | 19511T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter                       | XKC19512TN             | 19512TN                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                  | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-----------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Small S, Tethered Cap, Non Port               |                        |                         |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Gibeck Iso-Gard HEPA Light Port               | XKC28001               | 28001                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port               | XKG28001               | 28001                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port               | XKC28002               | 28002                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port               | XKG28002EU             | 28002EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port, Tethered Cap | XKC28001T              | 28001T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port, Tethered Cap | XKC28002T              | 28002T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light                    | XKC28012               | 28012                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light                    | XKG28012EU             | 28012EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light                    | XKC28022               | 28022                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light                    | XKG28022EU             | 28022EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                               | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Iso-Gard HEPA Small A               | XKC28051               | 28051                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small A               | XKC28052               | 28052                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S               | XKC28061               | 28061                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S               | XKG28061               | 28061                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S               | XKC28062               | 28062                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S               | XKG28062EU             | 28062EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S, Tethered Cap | XKC28062T              | 28062T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Anest-Guard                         | XKC28812               | 28812                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Hudson RCI Bacterial/Viral Filter          | XKC41605               | 41605                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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**Table 7: Heat & Moisture Exchanger (HME) Filter products**

| Product Name                                         | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Humid-Vent Filter Pedi                        | XKC11011               | 11011                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi                        | XKE11011               | 11011                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi                        | XKC11012               | 11012                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi, Tethered Cap          | XKC11011T              | 11011T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi, Tethered Cap          | XKC11012T              | 11012T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi Straight               | XKC12011               | 12011                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi Straight               | XKC12012               | 12012                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Pedi Straight, Tethered Cap | XKC12011T              | 12011T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                     | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Humid-Vent Filter Compact A               | XKC18401               | 18401                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact A               | XKC18402               | 18402                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact A, Tethered Cap | XKC18401T              | 18401T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact A, Tethered Cap | XKC18402T              | 18402T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small A                 | XKC18501               | 18501                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small A                 | XKI18502               | 18502                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small A                 | XKC18502EU             | 18502EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small                   | XKC18501T              | 18501T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                     | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| A, Tethered Cap                                  |                        |                         |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Gibeck Humid-Vent Filter Small A, Tethered Cap   | XKC18502T              | 18502T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S               | XKC19401               | 19401                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S               | XKC19402               | 19402                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S, Tethered Cap | XKC19401T              | 19401T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S, Tethered Cap | XKC19402T              | 19402T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S                 | XKC19501               | 19501                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S                 | XKI19502               | 19502                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                             | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Humid-Vent Filter Small S                         | XKC19502EU             | 19502EU                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S, Tethered Cap           | XKC19501T              | 19501T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S, Tethered Cap, Non Port | XKC19502TN             | 19502TN                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Light S                         | XKC19932               | 19932                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent HEPA                                   | XKC29001               | 29001                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent HEPA, Tethered Cap                     | XKC29001T              | 29001T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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**Table 8: Bacterial Viral Filter with Catheter Mount Products**

| Product Name                                                   | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|----------------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Iso-Gard Filter S with Expandi-Flex/Elbow, Tethered Cap | XKC19012T              | 19012T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S with Expandi-Flex, Tethered Cap       | XKC19261T              | 19261T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S with Expandi-Flex, Tethered Cap       | XKC19262T              | 19262T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard Filter S with Expandi-Flex, Tethered Cap       | XKC19272T              | 19272T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port with Expandi-Flex              | XKC28031               | 28031                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port with Expandi-Flex              | XKC28041               | 28041                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port with Expandi-Flex              | XKE28041               | 28041                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Light Port with Expandi-Flex              | XKC28042               | 28042                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                                    | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|-----------------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Iso-Gard HEPA Light Port with Expandi-Flex, Tethered Cap | XKC28042T              | 28042T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S with Expandi-Flex, Tethered Cap    | XKC28081T              | 28081T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S with Expandi-Flex, Tethered Cap    | XKG28081T              | 28081T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S with Expandi-Flex, Tethered Cap    | XKC28082T              | 28082T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Iso-Gard HEPA Small S with Expandi-Flex, Tethered Cap    | XKG28082T              | 28082T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Filter + Catheter Mount                                  | XKD191667S             | 191667-000100           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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**Table 9: HME Filter with Catheter Mount products**

| Product Name                                                              | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|---------------------------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck Humid-Vent Pedi + Flex                                             | XKE11021               | G11021C                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small A with Expandi-Flex                        | XKC18602               | 18602                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex/Swivel               | XKC19042               | 19042                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex/Swivel, Tethered Cap | XKC19042T              | 19042T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Smooth-Flo/Swivel                 | XKC19061               | 19061                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex & Mask Elbow         | XKC19092               | 19092                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter                                                  | XKC19132               | 19132                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                                                       | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|--------------------------------------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Compact A with Expandi-Flex                                        |                        |                         |                          |                                   |                                         |                   |                |                                    |                                    |                               |                                                 |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex and Swivel    | XKC19142               | 19142                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S with Expandi-Flex, Tethered Cap   | XKC19522T              | 19522T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex               | XKC19611               | 19611                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex               | XKC19621               | 19621                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex               | XKE19621               | G19621C                 | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Compact S with Expandi-Flex, Tethered Cap | XKC19622T              | 19622T                  | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck Humid-Vent Filter Small S with Expandi-Flex and Elbow       | XKC19662               | 19662                   | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |

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| Product Name                       | Product Code (MY code) | Product Code (SAP code) | MDD EC Certificate(s) No | MDD EC Certificate(s) Expiry Date | End date for Extended Transition Period | MDR Product Class | MDR Class Rule | MDR Conformity Assessment Route(s) | Substitute Devices (if applicable) | Scheduled MDR Submission Date | Device Schedule and/or Approved Quote Reference |
|------------------------------------|------------------------|-------------------------|--------------------------|-----------------------------------|-----------------------------------------|-------------------|----------------|------------------------------------|------------------------------------|-------------------------------|-------------------------------------------------|
| Gibeck HME Filter + Catheter Mount | XKD191302              | 191302-500150           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount | XKD191655S             | 191655-000050           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount |                        | 191655-000100           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount |                        | 191655-000150           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount | XKD191657              | 191657-000150           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount | XKD191658S             | 191658-000100           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount |                        | 191658-000150           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |
| Gibeck HME Filter + Catheter Mount | XKD191771C             | 191771-517150           | 50076-16-08              | 26 May 2024                       | 31 Dec 2028                             | Ila               | Rule 2         | Annex IX                           | N/A                                | Jan 2026                      | A23031167                                       |