Leaders in enteral delivery

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Medicina Limited
Manufacturer address and contact details	Units 2-4 Rivington View Business Park, Station Road, Blackrod, Bolton, BL6 5BN, United Kingdom
Single Registration Number (SRN) (if available)	UK-MF-000041402

Authorised Representative name (if applicable)	HMC Premedical S.p.A
Authorised Representative address and contact details	Via Bosco 1/3, 41037, Mirandola (MO), Italy
Single Registration Number (SRN) (if available)	IT-AR-000029439

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:
  - ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  - ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

- ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

- ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

- ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- ☒ A QMS in accordance with Article 10(9) MDR is in place.
- ☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:
Medicina Limited
Bolton, 02/08/2024

Tracey Macdonald
Managing Director and PRRC
Tracey.macdonald@medicina.co.uk

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile (disposable) and non-sterile (reusable) Oral Tip and Enteral Syringes (without needles) **REF:** PE01 OT10 PE25 OT20 PE05 OTH005 PE10 OTH01 PE20 OTH25 PE30 OTH05 PE60 OTH10 PE60B OTH20 OT005 OTB005 OT01 OTB01 OT01LD OTB25 OT25 OTB05 OT25LD OTB10 OT05 OTB20	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile (disposable) and non-sterile (reusable) ENFit Enteral Syringes (without needles) **REF:** LPE01LD LPE100 LPE25LD LHE01LD LPE05 LHE25LD LPE10 LHE05 LPE20 LHE10 LPE30 LHE20 LPE60 LHE60	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A
Sterile disposable luer lock and luer slip intravenous syringes and intravenous insulin syringes and accessories **REF:** IVS01 IVL01 IVS03 IVL03 IVS05 IVL05 IVS10 IVL10 IVS10E IVL20 IVS20 IVL30 IVS30 IVL60 IVS60 IVL60INS IVS01INS	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A

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Sterile disposable blunt fill and blunt fill filter needles **REF:** BN01 BN02	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A
ENFit Nasogastric Feeding Tubes for short term **REF:** CG10/120 CG6/80 CG10/80 CG6/80W CG10/160 CG8/120 CG10/80W CG8/40 CG12/80 CG8/50 CG12/80W CG8/80 CG12/120 CG8/80W CG14/80 CG4/90 CG4/40 CG4/120 CG4/50 CG4/160 CG4/50W CG6/90 CG4/80 CG6/160 CG5/40 RT10/100C CG5/50 RT12/100C CG5/80 RT14/100C CG6/100 RT16/100C CG6/120 RT18/100C CG6/40 RT20/100C CG6/50 RT8/80C CG6/50W RT6/80C	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A

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ENFit Nasogastric Feeding Tubes for Long term use **REF:** NGP10/120C NGP10/120CW NGP10/85C NGP10/85CW NGP10/95YC NGP12/100C NGP12/120C NGP12/120CW NGP12/85C NGP12/85CW NGP12/95YC NGP14/120C NGP14/120CW NGP14/85C NGP14/95YC NGP16/120C NGP6/55C NGP6/75C NGP6/85C NGP6/95YC NGP8/120C NGP8/120CW NGP8/55C NGP8/75C NGP8/85C NGP8/85CW NGP8/95YC	GB19-964955	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A
Sterile Silo Bag and Dressing for the treatment of Gastroschisis **REF:** SB03 SB35 SB04 SB45 SB05 SB06	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A

[1] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Sterile Ante-grade Continence Enema (ACE), Stoma stoppers for antegrade continence **REF:** AP8/15 AP12/30 AP8/30 AP12/60 AP8/60 AP12/100 AP10/15 AP14/30 AP10/30 AP14/60 AP10/60 AP14/100	GB19-964955	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A
Sterile ACElok Ace Stopper dressing **REF:** SD03	GB19-964577	24/05/2024	1639 SGS Belgium	0051 IMQ S.p.A.	31/12/2028	N/A

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