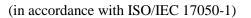


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| | ponsibility, that the product listed below ne European Parliament and of the Counc | · | |
|---|--|----------------------|--|
| Document Number 80029129 | Version D | | |
| Product Name | Two-Piece Blood Pressure Cuffs | | |
| Manufacturer's Name and Business Address | Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA | SRN: US-MF-000013394 | |
| Declaration of Conformity Validity | ISO 13485 #314505 MP2016 Expiry Date: 2024-11-07 | | |
| EC REP | Welch Allyn Limited, Navan Business Park, Dublin Road, Navan, Co. Meath, C15 AW22 Ireland | SRN: IE-AR-000000768 | |
| Object of the declaration | Two Piece Blood Pressure Cuffs | | |
| Intended Purpose | Welch Allyn Pediatric through Adult Blood Pressure cuffs are non-invasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients. | | |
| Medical Device Conformity Assessment Route Annex | Annex II and Annex III | | |
| Medical Device Classification | Class I | | |
| Medical Device Classification Rule | Rule I | | |
| Standards | Refer to Appendix A | | |





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| REF # | 901043: Blood Pressure Cuff, Reusable | | |
|---------------------|---------------------------------------|--|--|
| | 4500-02 | | |
| | 4500-03 | | |
| | 5200-01 | | |
| | 5200-02 | | |
| | 5082-01 | | |
| | 5082-02 | | |
| | 5082-03 | | |
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| | 5082-44 | | |
| | 5082-45 | | |
| | 5082-77 | | |
| | 5082-78 | | |
| | 45-15-389 | | |
| | 45-22-189 | | |
| | 45-23-189 | | |
| | 47-15-389 | | |
| | 47-22-189 | | |
| | 47-23-189 | | |
| | | | |
| GMDN Code and Term | 34978 - Blood Pressure Cuff, Reusable | | |
| UMDNS Code and Term | 11072 - Cuffs | | |
| Basic UDI-DI | 0732094GMN901043EY | | |

DECLARATION OF CONFORMITY



(in accordance with ISO/IEC 17050-1)

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| Approval | | |
|---|------------------|---------------------------|
| DocuSigned by: | | |
| katherine love | | |
| Signer Name: Katherine Love Signing Reason: I approve this document Signing Time: December 8, 2022 9:55:08 AM EST | | |
| BB8F4DB0044F42B2B2541C9071BCB69A | December 8, 2022 | 2 11:24:01 AM EST |
| | | Skaneateles Falls, NY USA |
| Katherine Love | Date | Place of Issue |
| Principal Specialist, Regulatory Affairs | | |

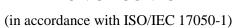


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Appendix A: Standards and Common Specifications

| Standards Applied | Number | Version/Date of Issue | Title |
|---------------------|---------------------|-----------------------|--|
| Regulation 2017/745 | EN ISO 13485 | 2016 | Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes |
| | EN ISO 15223- 1 | 2016 | Medical Devices - Symbols to be Used with medical Device Labels, Labelling and Information to be Supplied - Part 1: General Requirements |
| | EN ISO 10993- 1 | 2018 | Biological evaluation of medical devices - Part 1: Evaluation and testing |
| | EN ISO 10993- 5 | 2009 | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity |
| | EN ISO 10993- 10 | 2013 | Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization |
| | EN ISO 81060- 1 | 2012 | Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non- automated measurement type |
| | EN 80369-5 | 2016 | Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications |
| | EN 62366-1 | 2015 | Medical Devices - Part 1: Application of Usability Engineering to Medical Devices |

DECLARATION OF CONFORMITY





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Document Change History

| 2004 ment change motory | | | | | | |
|-------------------------|--|-------------|------------|--|--|--|
| Version | Description | Author | Date | | | |
| A | Initial Version. This DoC supersedes previous 2-Piece Cuff DoC DIR 80016679 which now contains Flexiport Reusable Cuffs only. | K Ockenfels | 2021-09-30 | | | |
| В | Added Intended Purpose statement and removed 14971 standard, not needed. | K Ockenfels | 2021-11-18 | | | |
| С | Removed Bladder only part numbers, due not contain a CE Mark accessories only. Removed 7052-35 and 7052-36 per marketing products will move to OB. | K Ockenfels | 2022-01-5 | | | |
| D | DoC expiration date to align with EN ISO 13485 certificate. | D. Sharma | 2022-12-07 | | | |