MEDIST

MEDical Suction Technique

# EU - DECLARATION OF CONFORMITY


**MEDIST, s.r.o.**

Petrusovskeho 455/4

06601 Humenne

Slovak Republic

SRN: SK-MF-000004422


**as a manufacturer issues the EU declaration of conformity under the sole responsibility of the manufacturer and declares that medical devices:**

| | | | |
|---|---|---|---|
| **Product Name:** | *Medical suction unit MEVACS* | | |
| **Basic UDI-DI:** | *8588009103Mevacs9W* | | |
| **Product group:** | ***Product name*** | ***Nomenclature*** | ***UDI-DI*** |
| | *MEVACS M20-230/12V* | *72006.01* | *08588009103080* |
| | *MEVACS M20* | *72002.00* | *08588009103059* |
| | *MEVACS M30* | *72002.01* | *08588009103066* |
| | *MEVACS M20, MOD-1* | *72002.03* | *08588009103158* |
| | *MEVACS M30, MOD-1* | *72002.05* | *08588009103165* |
| | *MEVACS M20D* | *72005.00* | *08588009103110* |
| | *MEVACS M30-230/12V* | *72006.02* | *08588009103097* |
| | *MEVACS M38* | *72001.00* | *08588009103035* |
| | *MEVACS M46* | *72001.01* | *08588009103042* |
| | *MEVACS M38, MOD-1* | *72001.03* | *08588009103134* |
| | *MEVACS M46, MOD-1* | *72001.04* | *08588009103141* |
| | *MEVACS M90* | *72001.02* | *08588009103103* |
| | *MEVACS 40* | *72000.00* | *08588009103011* |
| | *MEVACS 50* | *72000.01* | *08588009103028* |
| | *MEVACS 40, MOD-1* | *72000.02* | *08588009103127* |
| | *MEVACS S30/30* | *72004.00* | *08588009103073* |
| **Intended Purpose:** | *Medical suction units MEVACS are designed for suction liquids, blood and secretions, for creating vacuums in body cavities and the like.* | | |






**MEDIST s.r.o., Petrusovskeho 4, 06601 Humenne, Slovakia**

ID #: 36168513, Tax ID #: 2020038702, VAT #: SK2020038702, Bank: VUB a.s. Humenne, IBAN: SK73 0200 0000 0012 1831 1455

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**are in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council and the relevant standards and common specifications set out in the technical documentation.**

| | |
|---|---|
| **Applicable regulation/s:** | *REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL* |
| **Risk class:** (According to Annex VIII Medical Device Regulation 2017/745) | *Class IIa according to Rule 12* |
| **Conformity assessment procedure:** | *Annex IX of the Regulation (EU) 2017/745 (MDR)* |
| **List of Harmonized Standards applied:** | *STN EN 60601-1/A12:2016*<br>*STN EN 60601-1-2:2016*<br>*IEC 60601-1:2005 + Corr. 1:2006 + Corr.2:2007 + AM1:2012*<br>*STN EN 1041+A1:2014*<br>*STN EN ISO 10079-1:2009, STN EN ISO 10079-1:2016; ISO 10079-1:2022; STN*<br>*EN ISO 10079-4*<br>*EN ISO 14971:2019 a ISO/TR 24971:2020*<br>*STN EN ISO 15223-1:2021*<br>*STN EN 60812:2019*<br>*EN ISO 13485:2016* |
| **Notified body:** | *3EC International a.s.*<br>*Hranicna 18*<br>*821 05 Bratislava*<br>*Slovak Republic* |
| **Notified body No:** | *2265* |
| **EC certificate:**<br>**Place, Date:** | *No. 2022-MDR/QS-022*<br>*Bratislava, 27.09.2022* |

MEDIST, s.r.o.
Petrušovského 4, 066 01 Humenné, Slovakia
Reg. No.: 36168513
VAT No.:SK2020038702

**Place and date of declaration:**
*Humenné, 27.09.2022*

**Jan Kornucik**
Sales Director, Responsible person acc. MDR Art. 15



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