

# EC - DECLARATION OF CONFORMITY

**We, manufacturer: MEDIST, s.r.o.,** Petrusovskeho 455/4, 06601 Humenne, Slovak Republic

declare under our sole responsibility that the medical device, **Medical suction unit MEVACS** with accessories, models:

| MODELS             | REF                                       |
|--------------------|---|
| Mevacs 40          | 72000.00 / 72300.00                       |
| Mevacs 40, MOD-1   | 72000.02 / 72300.02                       |
| Mevacs 50          | 72000.01 / 72300.01                       |
| Mevacs M20         | 72002.00 / 72002.02 / 72302.00 / 72302.02 |
| Mevacs M20, MOD-1  | 72002.03 / 72002.04 / 72302.03 / 72302.04 |
| Mevacs M30         | 72002.01 / 72302.01                       |
| Mevacs M30, MOD-1  | 72002.05 / 72302.05                       |
| Mevacs M38         | 72001.00 / 72301.00                       |
| Mevacs M38, MOD-1  | 72001.03 / 72301.03                       |
| Mevacs M46         | 72001.01 / 72301.01                       |
| Mevacs M46, MOD-1  | 72001.04 / 72301.04                       |
| Mevacs S30/30      | 72004.00 / 72304.00                       |
| Mevacs M20-230/12V | 72006.01 / 72006.04 / 72306.01            |
| Mevacs M30-230/12V | 72006.02 / 72306.02                       |
| Mevacs M20D        | 72005.00 / 72305.00                       |
| Mevacs M90         | 72001.02 / 72301.02                       |

meets all applicable requirements of the Directive 93/42/EEC.


**Classification:** Medical Device CLASS IIa (by Directive 93/42/EEC, Annex IX, Rule 11)

|  |   |
|--|---|
| <b>Name, address and identification number of Notified Body:</b> | 3EC International a.s.<br>Hranicna 18, 821 05 Bratislava, Slovak Republic<br>Notified Body No. 2265<br><b>CE 2265</b>           |
| <b>EC Certificate / Expiration Date:</b>                         | No. 2017-MDD/QS-037 / July 29, 2022   |
| <b>Conformity assessment procedure:</b>                          | Directive 93/42/EEC Annex V on medical products, passed by the commission on 14th June 1993, last amended on 5th September 2007 |

All supporting documentation is retained by the manufacturer.

Valid till further changes on the product until July 29, 2022.

**Place and date of issue:** Humenne, July 30, 2017

  
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**Jan Kornucik, Sales Director**