



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic  
Notified body No. 2265

## EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2022-MDR/QS-022

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

Petrušovského 455/4, 066 01 Humenné, Slovak Republic  
SRN No.: SK-MF-000004422

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

**Medical suction unit MEVACS**

**Basic UDI-DI: 8588009103Mevacs9W**

**Models: see Annex I**

**Intended purpose: Medical suction units MEVACS are designed for suction liquids, blood and secretions, for creating vacuums in body cavities and the like.**

**MD class IIa according to Rule 12**

meets the requirements on quality management system according to the Chapter I Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: **N/A**

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR051\_2022 from 7.9.2022, MD Clinical Evaluation Report No. MDR051\_2022 from 26.9.2022 and MD Audit Report No. SK 0525-MDR/22 from 26.9.2022. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **27.9.2022**  
Valid until: **27.9.2027**  
First issue: **27.9.2022**  
Revision: **00**  
History: **Annex III**

In Bratislava, Slovakia, 27.9.2022



  
**3EC International a.s.**  
**Katarina Tomin Srdošová, PhD.**  
Director of NB2265