



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.**

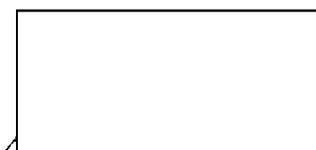
Conditions for or limitations to the validity of the certificate: **N/A**

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: **30.1.2025**  
Valid until: **27.9.2027**  
First issue: **27.9.2022**  
Revision: **01**  
History: **Annex III**



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

In Bratislava, Slovakia. 30.1.2025



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

issued for the company

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

Petrušovského 455/4, 066 01 Humenné, Slovak Republic

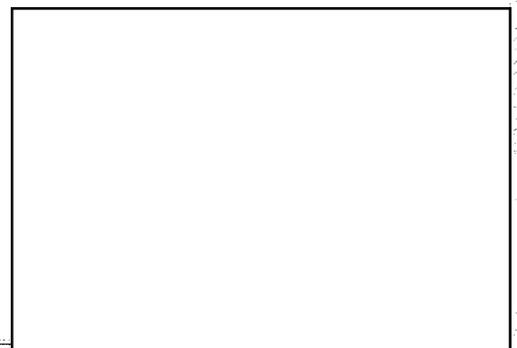
### List of medical devices covered by the EU Quality Management System Certificate:

Type No.	Trade Name	UDI-DI
MEVACS M20-230/12V	Medical suction unit MEVACS	08588009103080
MEVACS M20	Medical suction unit MEVACS	08588009103059
MEVACS M30	Medical suction unit MEVACS	08588009103066
MEVACS M20, MOD-1	Medical suction unit MEVACS	08588009103158
MEVACS M30, MOD-1	Medical suction unit MEVACS	08588009103165
MEVACS M20D	Medical suction unit MEVACS	08588009103110
MEVACS M30-230/12V	Medical suction unit MEVACS	08588009103097
MEVACS M38	Medical suction unit MEVACS	08588009103035
MEVACS M46	Medical suction unit MEVACS	08588009103042
MEVACS M38, MOD-1	Medical suction unit MEVACS	08588009103134
MEVACS M46, MOD-1	Medical suction unit MEVACS	08588009103141
MEVACS M90	Medical suction unit MEVACS	08588009103103
MEVACS 40	Medical suction unit MEVACS	08588009103011
MEVACS 50	Medical suction unit MEVACS	08588009103028
MEVACS 40, MOD-1	Medical suction unit MEVACS	08588009103127
<b>MEVACS S30/30</b>	<b>Medical suction unit MEVACS</b>	<b>08588009103073</b>

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In Bratislava, Slovakia, 30.1.2025  
Valid until 27.9.2027





**ANNEX II TO EU QUALITY MANAGEMENT SYSTEM  
CERTIFICATE No. 2022-MDR/QS-022**

issued for the company

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

Petrušovského 455/4, 066 01 Humenné, Slovak Republic

**Intended purpose of medical devices covered by the EU Quality Management System Certificate:**

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

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Katarína Tomášová, PhD.  
Director of NB2265

In Bratislava, Slovakia, 30.1.2025  
Valid until 27.9.2027



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

issued for the company

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

Petrušovského 455/4, 066 01 Humenné, Slovak Republic

### Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2022-MDR/QS-022	27.9.2022	MDR051_2022	Initially graded certification
01	2022-MDR/QS-022	30.1.2025	MDR051_2022	Administrative error

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**Katarina Tomin Srdošová, PhD.**  
Director of NB2265

In Bratislava, Slovakia, 30.1.2025  
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