



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-025/A

BISMED, s.r.o.

Registered office: Knínická 1577/8; 664 34 Kuřim, Czech Republic
Manufacturing site: Soškova 1562, 592 31 Nové Město na Moravě, Czech Republic
SRN No.: CZ-MF-000040871

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:

Suction Connecting Tube
(for detailed list of models and variants refer to Annex I)
Intended purpose: see Annex II
MD class IIa, Rule 2
(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of 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 Technical Documentation Assessment Report No. MDR619_2024 from 2025-03-19, Clinical Evaluation Report No. MDR619_2024 from 2025-03-19 and Audit Report No. SK-0815/25 from 2025-03-25 and Decision on MD Conformity Assessment No. MDR619_2024/A from 2026-03-03. 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: **2026-03-03**
Valid until: **2030-03-25**
First issue: **2025-03-25**
Revision: **01**
History: **see Annex III**




3EC International a. s.
Katarina Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-03-03



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-025/A

issued for the company

BISMED, s.r.o.

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

MD Name	Model	Variants – Sterile version
Suction Connecting Tube	Suction connecting tube CH25	REF: 07.068.25.150 Suction Connecting Tube Ch 25 – 1,5 m, Funnel/Funnel
		REF: 07.068.25.200 Suction Connecting Tube Ch 25 – 2 m, Funnel/Funnel
		REF: 07.068.25.250 Suction Connecting Tube Ch 25 – 2,5 m, Funnel/Funnel
		REF: 07.068.25.300 Suction Connecting Tube Ch 25 – 3m, Funnel/Funnel
		REF: 07.068.25.350 Suction Connecting Tube Ch 25 – 3,5m, Funnel/Funnel
		REF: 07.068.25.500 Suction Connecting Tube Ch 25 – 5m, Funnel/Funnel
		REF: 07.068.25.600 Suction Connecting Tube Ch 25 – 6m, Funnel/Funnel
		REF: 07.068.25.160 Suction Connecting Tube Ch 25 – 1,5m, Funnel/Vacuum Control
		REF: 07.068.25.186 Suction Connecting Tube Ch 25 – 1,8m, Funnel/Vacuum Control
		REF: 07.068.25.210 Suction Connecting Tube Ch 25 – 2m, Funnel/Vacuum Control
		REF: 07.068.25.260 Suction Connecting Tube Ch 25 – 2,5m, Funnel/Vacuum Control
		REF: 07.068.25.310 Suction Connecting Tube Ch 25 – 3m, Funnel/Vacuum
		REF: 07.068.25.359 Suction Connecting Tube Ch 25 – 2m, Funnel/tube part
		REF: 07.068.25.360 Suction Connecting Tube Ch 25 – 2,5m, Funnel/tube part
		REF: 07.068.25.375 Suction Connecting Tube Ch 25 – 3,5m, Funnel/tube part
		REF: 07.068.25.575 Suction Connecting Tube Ch 25 – 5m, Funnel/tube part



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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-03-03
Valid until 2030-03-25





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

MD Name	Model	Variants – Sterile version
Suction Connecting Tube	Suction connecting tube CH25	REF: 07.068.25.211 Suction Connecting Tube Ch 25 – 2m, Funnel/Vacuum Control free
		REF: 07.068.25.208 Suction Connecting Tube Ch 25 – 2m, adapted funnel/Vacuum Control
		REF: 07.068.25.180 Suction Connecting Tube Ch 25 – 1,8m, adapted funnel/Vacuum Control
		REF: 07.068.25.209 Suction Connecting Tube Ch 25 – 2m, adapted funnel/adapted funnel, Vacuum Control slid
		REF: 07.068.25.212 Suction Connecting Tube Ch 25 – 2m, adapted funnel/adapted funnel, Vacuum Control free
		REF: 07.068.25.125 Suction Connecting Tube Ch 25 – 1,25m, Funnel/Tube
		REF: 07.068.25.220 Suction Connecting Tube Ch 25 – 2m, Funnel/Tube
		REF: 07.068.25.270 Suction Connecting Tube Ch 25 – 2,5m, Funnel/Tube
		REF: 07.068.25.320 Suction Connecting Tube Ch 25 – 3m, Funnel/Tube
		REF: 07.068.25.420 Suction Connecting Tube Ch 25 – 4m, Funnel/Tube
		REF: 07.068.25.213 Suction Connecting Tube Ch 25 – 1,8 m, Vacuum Control/Tube
		REF: 07.068.25.100 Suction Connecting Tube Ch 25 - 1m, Tube/Tube
		REF: 07.068.25.201 Suction Connecting Tube Ch 25 -2m, Tube/Tube
		REF: 07.068.25.251 Suction Connecting Tube Ch 25 – 2,5m, Tube/Tube
		REF: 07.068.25.301 Suction Connecting Tube Ch 25 - 3m, Tube/Tube
		REF: 07.068.25.425 Suction Connecting Tube Ch 25 - 4m, Tube/Tube
		REF: 07.068.25.525 Suction Connecting Tube Ch 25 - 5m, Tube/Tube
REF: 07.068.25.330 Suction Connecting tube Ch 25 – 3m Tube part/ Tube part		



Katarína Tomin Srdošová, PhD.
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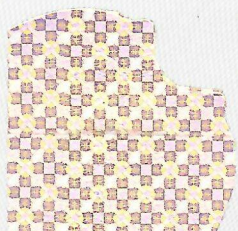
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		REF: 99.068.25.250 Suction Connecting Tube Ch 25 – 2,5 m, Funnel/Funnel
		REF: 99.068.25.300 Suction Connecting Tube Ch 25 – 3m, Funnel/Funnel
		REF: 99.068.25.350 Suction Connecting Tube Ch 25 – 3,5m, Funnel/Funnel
		REF: 99.068.25.500 Suction Connecting Tube Ch 25 – 5m, Funnel/Funnel
		REF: 99.068.25.600 Suction Connecting Tube Ch 25 – 6m, Funnel/Funnel
		REF: 99.068.25.160 Suction Connecting Tube Ch 25 – 1,5m, Funnel/Vacuum Control
		REF: 99.068.25.186 Suction Connecting Tube Ch 25 – 1,8m, Funnel/Vacuum Control
		REF: 99.068.25.210 Suction Connecting Tube Ch 25 – 2m, Funnel/Vacuum Control
		REF: 99.068.25.260 Suction Connecting Tube Ch 25 – 2,5m, Funnel/Vacuum Control
		REF: 99.068.25.310 Suction Connecting Tube Ch 25 – 3m, Funnel/Vacuum Control
		REF: 99.068.25.359 Suction Connecting Tube Ch 25 – 2m, Funnel/hose part
		REF: 99.068.25.360 Suction Connecting Tube Ch 25 – 2,5m, Funnel/hose part
		REF: 99.068.25.375 Suction Connecting Tube Ch 25 – 3,5m, Funnel/hose part
		REF: 99.068.25.575 Suction Connecting Tube Ch 25 – 5m, Funnel/hose part
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		REF: 99.068.25.220 Suction Connecting Tube Ch 25 – 2m, Funnel/Tube
		REF: 99.068.25.270 Suction Connecting Tube Ch 25 – 2,5m, Funnel/Tube
		REF: 99.068.25.320 Suction Connecting Tube Ch 25 – 3m, Funnel/Tube
		REF: 99.068.25.420 Suction Connecting Tube Ch 25 – 4m, Funnel/Tube
		REF: 99.068.25.213 Suction Connecting Tube Ch 25 – 1,8 m, Vacuum Control/Tube
		REF: 99.068.25.100 Suction Connecting Tube Ch 25 - 1m, Tube/Tube
		REF: 99.068.25.201 Suction Connecting Tube Ch 25 - 2m, Tube/Tube
		REF: 99.068.25.251 Suction Connecting Tube Ch 25 – 2,5m, Tube/Tube
		REF: 99.068.25.301 Suction Connecting Tube Ch 25 - 3m, Tube/Tube
		REF: 99.068.25.425 Suction Connecting Tube Ch 25 - 4m, Tube/Tube
		REF: 99.068.25.525 Suction Connecting Tube Ch 25 - 5m, Tube/Tube
REF: 99.068.25.330 Suction Connecting tube Ch 25 – 3m Tube part/ Tube part		



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Katarína Tomin Srdošová, PhD.
Director of NB 2265

In Bratislava, Slovak Republic, 2026-03-03
Valid until 2030-03-25



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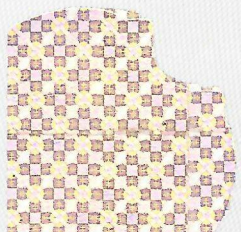
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		REF: 07.068.30.300 Suction Connecting Tube Ch 30 – 3 m, Funnel/Funnel
		REF: 07.068.30.350 Suction Connecting Tube Ch 30 – 3,5m, Funnel/Funnel
		REF: 07.068.30.400 Suction Connecting Tube Ch 30 – 4 m, Funnel/Funnel
		REF: 07.068.30.500 Suction Connecting Tube Ch 30 – 5 m, Funnel/Funnel
		REF: 07.068.30.600 Suction Connecting Tube Ch 30 – 6 m, Funnel/Funnel
		REF: 07.068.30.160 Suction Connecting Tube Ch 30 – 1,5m, Funnel/Vacuum Control
		REF: 07.068.30.186 Suction Connecting Tube Ch 30 – 1,8m, Funnel/Vacuum Control
		REF: 07.068.30.210 Suction Connecting Tube Ch 30 – 2 m, Funnel/Vacuum Control
		REF: 07.068.30.260 Suction Connecting Tube Ch 30 – 2,5m, Funnel/Vacuum Control
		REF: 07.068.30.310 Suction Connecting Tube Ch 30 – 3 m, Funnel/Vacuum Control
		REF: 07.068.30.410 Suction Connecting Tube Ch 30 – 4 m, Funnel/Vacuum Control
		REF: 07.068.30.510 Suction Connecting Tube Ch 30 – 5 m, Funnel/Vacuum Control



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Suction Connecting Tube	Suction connecting tube CH30	REF: 07.068.30.610 Suction Connecting Tube Ch 30 – 6 m, Funnel/Vacuum Control
		REF: 07.068.30.302 Suction Connecting Tube CH 30 – 3 m, Funnel/Funnel, Vacuum Control free
		REF: 07.068.30.152 Suction Connecting Tube CH 30 – 1,5 m, Funnel/Tube
		REF: 07.068.30.270 Suction Connecting Tube Ch 30 – 2,5m, Funnel/Tube
		REF: 07.068.30.320 Suction Connecting Tube Ch 30 – 3 m, Funnel/Tube
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		REF: 07.068.30.520 Suction Connecting Tube Ch 30 – 5m, Funnel/Tube
		REF: 07.068.30.159 Suction Connecting Tube Ch 30 – 1,5m, Vacuum Control /Tube
		REF: 07.068.30.217 Suction Connecting Tube Ch 30 – 2m, Funnel/Tube
		REF: 07.068.30.419 Suction Connecting Tube Ch 30 – 4m, Vacuum Control/Tube
		REF: 07.068.30.220 Suction Connecting Tube Ch 30 - 2m, Tube/Tube
REF: 07.068.30.325 Suction Connecting Tube Ch 30 - 3m, Tube/Tube		



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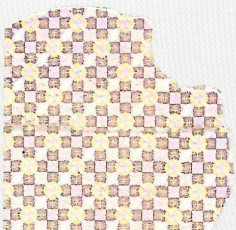
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In Bratislava, Slovak Republic, 2026-03-03
Valid until 2030-03-25





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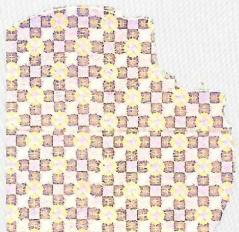
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Katarína Tomín Srdošová, PhD.
Director of NB 2265



ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-025/A

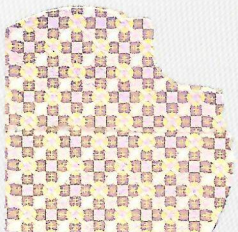
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Intended purpose of medical devices covered by the EU Quality Management System Certificate:

Aspiration and remove of body fluid in surgery.



Page 9 of 10

In Bratislava, Slovak Republic, 2026-03-03
Valid until 2030-03-25

A handwritten signature in blue ink, appearing to read 'Katarína Tomin Srdošová'.

Katarína Tomin Srdošová, PhD.
Director of NB 2265



ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-025/A

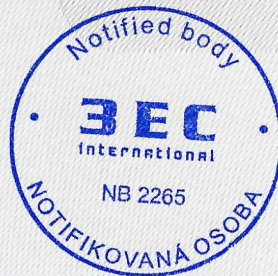
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Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-MDR/QS-025	2025-03-25	MDR619_2024	Initially granted certification
01	2025-MDR/QS-025/A	2026-03-03	MDR619_2024/A	Certificate supplemented - correction of the address according to the Commercial Register - missing descriptive number /8



Katarína Tomin Srdošová, PhD.
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