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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-024/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:

Wound drainage system
(for detailed list of models and variants refer to Annex I)
Intended purpose: see Annex II
MD class IIa, Rule 12
(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. MDR618_2024 from 2025-03-19, Clinical Evaluation Report No. MDR618_2024 from 2025-03-19 and Audit Report No. SK-0815/25 from 2025-03-19 and Decision on MD Conformity Assessment No. MDR618_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**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovak Republic, 2026-03-03

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

©Tlačiareň cenín KASICO, a. s. Bratislava, KC25-00218

ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-024/A

issued for the company

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

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

Medical device name	Model	Variants
Wound drainage system	Vacuum bottle for wound drainage Redon with tube	REF: 05.000.22.799 - Vacuum bottle for wound drainage Redon with tube, round bottle 200 ml, OR System, Sterile
		REF: 05.000.22.801 - Vacuum bottle for wound drainage Redon with tube, square bottle 200 ml, OR System, Sterile
		REF: 05.000.22.803 - Vacuum bottle for wound drainage Redon with tube, round bottle 400 ml, OR System, Sterile
		REF: 99.000.22.799 - Vacuum bottle for wound drainage Redon with tube, round bottle 200 ml, OR System, Non Sterile
		REF: 99.000.22.801 - Vacuum bottle for wound drainage Redon with tube, square bottle 200 ml, OR System, Non Sterile
		REF: 99.000.22.803 - Vacuum bottle for wound drainage Redon with tube, round bottle 400 ml, OR System, Non Sterile
	Vacuum bottle for wound drainage Redon without tube	REF: 05.000.22.798 Vacuum bottle for wound drainage Redon without tube, round bottle 200 ml, Ward System, Sterile
		REF: 05.000.22.800 Vacuum bottle for wound drainage Redon without tube, square bottle 200 ml, Ward System, Sterile
		REF: 05.000.22.802 Vacuum bottle for wound drainage Redon without tube, round bottle 400 ml, Ward System, Sterile
		REF: 99.000.22.798 Vacuum bottle for wound drainage Redon without tube, round bottle 200 ml, Ward System, Non Sterile
		REF: 99.000.22.800 Vacuum bottle for wound drainage Redon without tube, square bottle 200 ml, Ward System, Non Sterile
		REF: 99.000.22.802 Vacuum bottle for wound drainage Redon without tube, round bottle 400 ml, Ward System, Non Sterile

Notified body · 3EC international · NB 2265 · NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

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

©Tlačiareň cenín KASICO, a. s. Bratislava, KC25-00218

ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-024/A

issued for the company

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

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

A source of vacuum energy associated with the extraction of the extract into a drainage bottle.

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Page 2 of 3

Katarína Tomin Srdošová, PhD.
Director of NB 2265

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

©Tlačiareň cenín KASICO, a. s. Bratislava, KC25-00218

ANNEX III TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2025-MDR/QS-024/A

issued for the company

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

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application Number for Conformity Assessment	Description
00	2025-MDR/QS-024	2025-03-25	MDR618_2024	Initially granted certification
01	**2025-MDR/QS-024/A**	**2026-03-03**	**MDR618_2024/A**	**Certificate supplemented - correction of the address according to the Commercial Register - missing descriptive number /8**

Notified body
NB 2265
NOTIFIKOVANÁ OSOBA

Katarína Tomin Srdošová, PhD.
Director of NB 2265

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

©Tlačiarne corpin KASICO, a. s. Bratislava, KC25 09218