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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-004

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Braided & Coated Polyglycolic Acid Suture
Sterile Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class III, Rule 8
(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. MDR369_2024 from 23.10.2024, Clinical Evaluation Report No. MDR369_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-005

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Braided & Coated Polyglactin 910 Suture
Sterile Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class III, Rule 8
(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. MDR370_2024 from 23.10.2024, Clinical Evaluation Report No. MDR370_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

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

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

3EC International NB 2265 3EC International NB 2265 3EC International NB 2265

3EC International

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-006

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Monofilament Poliglecaprone 25 Suture
Sterile Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class III, Rule 8
(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. MDR371_2024 from 23.10.2024, Clinical Evaluation Report No. MDR371_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 31.01.2025

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

3EC International NB 2265 3EC International NB 2265 3EC International NB 2265

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-007

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Monofilament Polydioxanone Suture
Sterile Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class III, Rule 8
(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. MDR372_2024 from 23.10.2024, Clinical Evaluation Report No. MDR372_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-008

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Non-Absorbable Synthetic Suture
Sterile Non-Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class IIb, Rule 8
(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. MDR373_2024 from 23.10.2024, Clinical Evaluation Report No. MDR373_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

3EC International NB 2265 3EC International NB 2265 3EC International NB 2265

3EC®
international

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-009

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

MONOFILAMENT POLYPROPYLENE MESH
Non-Absorbable Sterile Surgical Mesh
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class III, Rule 8
(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. MDR376_2024 from 23.10.2024, Clinical Evaluation Report No. MDR376_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

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

In Bratislava, Slovakia, 31.01.2025

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

3EC International NB 2265 3EC International NB 2265 3EC International NB 2265

3EC®
international

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-010

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Non-Absorbable Non-Synthetic Suture
Sterile Non-Absorbable Surgical Suture
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class IIb, Rule 8
(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. MDR377_2024 from 23.10.2024, Clinical Evaluation Report No. MDR377_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC international NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21

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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE
No. 2025-MDR/QS-011

Unisur Lifecare Private Limited

No. 15/1,2,3 Acharya Industrial Complex, Andrahalli Main Road, Vishwaneedam Post, Bengaluru, Bengaluru Urban, Karnataka – 560091, India
SRN No.: IN-MF-000008184
Name of the Authorized representative: MEDDEVICES LIFESCIENCES B.V.
Keizersgracht 482, 1017 EG, Amsterdam, The Netherlands
SRN No.: NL-AR-000000594

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:

Sterile Bonewax
Sterile Non-absorbable Bonewax
(for detailed list refer to Annex I)
Intended purpose: see Annex II
MD class IIb, Rule 8
(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. MDR379_2024 from 23.10.2024, Clinical Evaluation Report No. MDR379_2024 from 23.10.2024 and Audit Report No. SK-0500/24 from 04.01.2025. 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. For the placing on the market of the MDs which this certificate covers, the EU Technical Documentation Assessment Certificate issued in accordance with the Regulation (EU) 2017/745 on medical devices as amended is required. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.

Valid from: **31.01.2025**
Valid until: **31.01.2030**
First issue: **31.01.2025**
Revision: **00**
History: **see Annex III**

Notified body 3EC International NB 2265 NOTIFIKOVANÁ OSOBA

In Bratislava, Slovakia, 31.01.2025

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

©Tlačiareň cenín KASICO, a. s. Bratislava, 110-141-21