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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. [redacted]

[redacted]

[redacted] India

SRN No.: [redacted]

Name of the Authorized representative:

[redacted]

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:

Gauze Swab (With and Without X-Ray Detectable Thread)
Product Name: Gauze Swab (Without X-Ray Detectable Thread) (Non-Sterile), Gauze Swab (With X-Ray Detectable Thread) (Non-Sterile), Gauze Swab (Without X-Ray Detectable Thread) (Sterile), Gauze Swab (With X-Ray Detectable Thread) (Sterile)
Intended purpose: Annex II
MD class IIa
(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. [redacted] 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. [redacted] from March 15, 2023, MD Clinical Evaluation Report No. [redacted] from April 14, 2023 and MD Audit Report No. [redacted] from August 12, 2023. 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: [redacted]
Valid until: [redacted] **2028**
First issue: [redacted]
Revision: **00**
History: **Annex III**

Notified body · 3EC International · NB [redacted] · NOTIFIKOVANÁ OSOBA

3EC International a.s.
[redacted] **PhD.**
Director of [redacted]

In Bratislava, Slovakia, August 21, 2023