



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

No. _____

India

SRN No.: _____

Name of the Authorized representative: _____

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:

X-Ray Detectable Abdominal Pad

Product Name: X-Ray Detectable Abdominal Pad (Non-sterile), X-Ray Detectable Abdominal Pad (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.

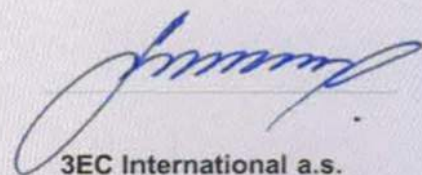
Notified body No. _____ has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. _____ from March 15, 2023, MD Clinical Evaluation Report No. _____ from April 14, 2023 and MD Audit Report No. _____ 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: _____
Valid until: _____ 2028
First issue: _____
Revision: 00
History: Annex III




3EC International a.s.
, PhD.

Director of _____

In Bratislava, Slovakia, August 21, 2023