



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

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-047

MEDICA FILTER spol. s r.o.

Head Office: Smetanova 421, 341 92 Kašperské Hory, Czech Republic

Manufacturing site: Smetanova 421, 341 92 Kašperské Hory, Czech Republic

SRN No.: CZ-PR-000044603

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 system / procedure pack:

Procedure pack

Trade Name: Sterile surgical procedure packs

Type / variant: See Annex I

Intended purpose: See Annex II

MD class Is

(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I 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**

For systems / procedure packs, the audit by the NB2265 of the quality management system was limited to the aspects of the procedure relating to ensuring sterility until the sterile packaging is opened or damaged.

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 system / procedure pack and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned system / procedure pack is stated in the MD Audit Report No. SK-0764/24 from 11.7.2024. Information on all examinations and tests performed is stated in the abovementioned report and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned system / procedure pack. The certificate validity is conditional upon fulfilment of relevant legal requirements by the natural / legal person combining the system / procedure pack.



Valid from: **20.11.2024**
Valid until: **16.07.2029**
First issue: **16.07.2024**
Revision: **01**
History: **See Annex III**

In Bratislava, Slovakia, 20.11.2024



3EC International a.s.
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Director of NB2265