



Notified Body No 1023
INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, a.s.
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EU Quality Management System Certificate No. 25 0336 QR/NB

Quality management system of the company

BATIST Medical Productions s.r.o.

Registered office address: **Nerudova 744, 549 41, Červený Kostelec,
Czech Republic**

SRN No. of the procedure packs producer: **CZ-PR-000023497**

is certified in accordance with the requirements of

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medical devices, Annex IX, Chapters I and III, and Article 22(3), related to systems and
procedure packs sterilized in accordance with their manufacturers' instructions

for the following procedure packs range:

Sterile Sets

Notified Body No 1023 declares that it has assessed the quality management system of the
above-mentioned procedure packs producer in accordance with Annex IX, Chapters I and
III of the Regulation (EU) 2017/745 for the aspects related to the procedure to ensuring
sterility until the sterile packaging is opened or damaged, for the procedure packs range
covered by this certificate. The audited part of the quality management system complies with
the requirements of Regulation (EU) 2017/745 and is subject to regular surveillance audits.
A detailed description of the system elements, requirements and measures adopted by the
procedure packs producer is provided in the final report No. 803603041, which is issued
together with the present certificate.

Valid from: 2025-08-29

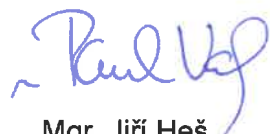
Valid until: 2030-08-28

Previous EU certificate No.: -

Previous EU certificate issue date: -

Date of issue: 2025-08-29




Mgr. Jiří Heš
Representative of Notified Body No 1023



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Annex to EU Certificate No. 25 0336 QR/NB
issued to the procedure packs producer:

BATIST Medical Productions s.r.o.
Nerudova 744, 549 41, Červený Kostelec, Czech Republic

Procedure packs producer's details:

Producer's company name: BATIST Medical Productions s.r.o.
Single registration number (SRN): CZ-PR-000023497
Registered office address: Nerudova 744, 549 41, Červený Kostelec,
Czech Republic
Production site address: Nerudova 744, 549 41, Červený Kostelec,
Czech Republic

Details of the authorised representative (if required):

Name of the EU authorised representative: -
Address of the EU authorised representative: -



Date of issue: 2025-08-29

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BATIST Medical Productions s.r.o.
Nerudova 744, 549 41, Červený Kostelec, Czech Republic

Product(s):

| | |
|----------------------|----------------------|
| Product name: | Surgical sets |
| Trademark(s): | - |
| Model(s): | - |
| Basic UDI-DI: | 8596222PP117Y |

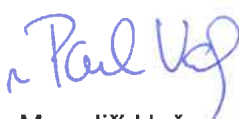
| | |
|----------------------|------------------------|
| Product name: | Orthopedic sets |
| Trademark(s): | - |
| Model(s): | - |
| Basic UDI-DI: | 8596222PP1384 |

| | |
|----------------------|--------------------------|
| Product name: | ENT + dental sets |
| Trademark(s): | - |
| Model(s): | - |
| Basic UDI-DI: | 8596222PP1486 |

| | |
|----------------------|---|
| Product name: | Gynecological, obstetric and urological sets |
| Trademark(s): | - |
| Model(s): | - |
| Basic UDI-DI: | 8596222PP1588 |

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issued to the procedure packs producer:

BATIST Medical Productions s.r.o.
Nerudova 744, 549 41, Červený Kostelec, Czech Republic

Product name: Neurological sets
Trademark(s): -
Model(s): -
Basic UDI-DI: 8596222PP168A

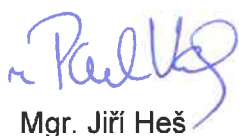
Product name: Ocular sets
Trademark(s): -
Model(s): -
Basic UDI-DI: 8596222PP178C

Product name: Cardio + angio sets
Trademark(s): -
Model(s): -
Basic UDI-DI: 8596222PP188E

Product name: Small ambulatory sets
Trademark(s): -
Model(s): -
Basic UDI-DI: 8596222PP111ZQ

Date of issue: 2025-08-29




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