



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 24 0234 QR/NB

Quality management system of the company

**BATIST Medical Productions s.r.o.**

**Nerudova 744, 549 41, Červený Kostelec, Czech Republic**

**SRN: CZ-MF-000023495**

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**

for the following device-range:

**Sterile gauze products  
Sterile cellulose wadding  
Sterile drapes**

Notified Body No 1023 declares that it has assessed the quality management system of the above-mentioned manufacturer in accordance with Annex IX, Chapters I and III of the Regulation (EU) 2017/745 for the aspects related to the establishing, securing and maintaining sterile conditions for the device-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 manufacturer is provided in the final report No. 803602946, which is issued together with the present certificate.

**Valid from:** 2024-06-26

**Valid until:** 2029-06-25

Previous EU certificate No.: --

Previous EU certificate issue date: --

Date of issue: 2024-06-26



Mgr. Jiří Heš

Representative of Notified Body No 1023



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issued to the manufacturer:

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**Manufacturer details:**


Manufacturer's company name: BATIST Medical Productions s.r.o.  
Single registration number (SRN): CZ-MF-000023495  
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: 2024-06-26



  
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**Product(s):**

**Product name:** Gauze compress sterile I.V.  
**Trademark(s):** STERILKOMPRES I.V.  
**Model(s):** STERILKOMPRES I.V 10 x 20 cm, packed per 2 pcs  
STERILKOMPRES I.V 10 x 10 cm, packed per 3 pcs  
STERILKOMPRES I.V 10 x 10 cm, packed per 2 pcs  
STERILKOMPRES I.V 10 x 10 cm packed per 1Y+2 pcs  
STERILKOMPRES I.V 10 x 10 cm packed per 10 pcs  
STERILKOMPRES I.V 7.5 x 7.5 cm packed per 2 pcs  
STERILKOMPRES I.V 5 x 5 cm packed per 10 pcs

**Class:** Is



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**Product name:** **Folded gauze cuttings with cellulose wadding**

**Trademark(s):** B-CUT (CELL)

**Model(s):** B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 20 x 10 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 20 x 10 cm packed per 3 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 20 x 20 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 24 x 7 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 24 x 7 cm packed per 4 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 15 x 30 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 10 x 10 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 10 x 24 cm packed per 2 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 10 x 24 cm packed per 3 pcs  
B-CUT(CELL) S Folded gauze cuttings with cellulose wadding 7 x 8 cm packed per 5 pcs

**Class:** Is

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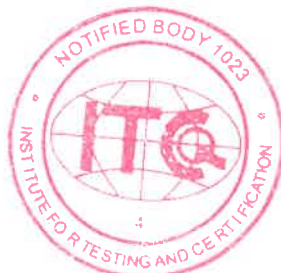
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**Product name:** Cotton pad in gauze wrapping  
**Trademark(s):** B-COMP S  
**Model(s):** B-COMP S Cotton pad in gauze wrapping 7 x 7 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 10 x 10 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 10 x 15 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 20 x 30 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 2, 10 x 10 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 2, 10 x 15 cm, packed per 2 pcs  
B-COMP S Cotton pad in gauze wrapping 2, 20 x 30 cm, packed per 2 pcs  
**Class:** Is

**Product name:** BURN BANDAGE  
**Trademark(s):** -  
**Model(s):** Burn bandage packed per 1 pc  
**Class:** Is

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**Product name:** Cellulose Wadding Tampon sterile  
**Trademark(s):** B-CELLIN S  
**Model(s):** B-CELLIN S Cellulose Wadding Tampon sterile per 2 pcs  
B-CELLIN S Cellulose Wadding Tampon sterile per 3 pcs  
**Class:** Is

**Product name:** Cellulose Wadding Tampon sterile  
**Trademark(s):** CELLIN S  
**Model(s):** CELLIN S Cellulose Wadding Tampon sterile per 20 pcs  
CELLIN S Cellulose Wadding Tampon sterile per 50 pcs  
CELLIN S Cellulose Wadding Tampon sterile per 2 pcs  
CELLIN S Cellulose Wadding Tampon sterile per 3 pcs  
CELLIN S Cellulose Wadding Tampon sterile per 10 pcs  
**Class:** Is



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**Product name:** Utility drape  
**Trademark(s):** Hospidrape  
**Model(s):** Utility drape Hospidrape 38 x 45 cm per 1 pc, sterile  
Utility drape Hospidrape 50 x 60 cm per 1 pc, sterile  
Utility drape Hospidrape 45 x 75 cm per 1 pc, sterile  
Utility drape Hospidrape 75 x 90 cm per 1 pc, sterile  
Utility drape Hospidrape 90 x 120 cm per 1 pc, sterile  
**Class:** Is

**Product name:** U drape with absorbent patch  
**Trademark(s):** -  
**Model(s):** U drape with absorbent patch 230 x 260 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Extremity drape  
**Trademark(s):** -  
**Model(s):** Extremity drape 230 x 300 cm, aperture 7 cm per 1 pc, sterile  
Extremity drape 230 x 300 cm, aperture 3.5 cm per 1 pc, sterile  
**Class:** Is

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**Product name:** Vertical drape  
**Trademark(s):** -  
**Model(s):** Vertical drape 240 x 330 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Angiography drape  
**Trademark(s):** -  
**Model(s):** Angiography drape 230 x 300 cm per 1 pc, sterile  
Angiography drape 220 x 300 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Ophthalmic drape  
**Trademark(s):** -  
**Model(s):** Ophthalmic drape 120 x 120 cm with incision film per 1 pc, sterile  
Ophthalmic drape 150 x 150 cm with incision film per 1 pc, sterile  
**Class:** Is



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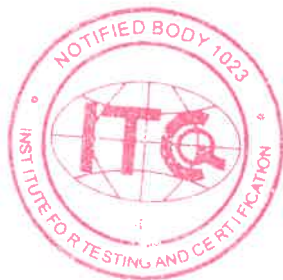
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**Product name:** Laparoscopy drape  
**Trademark(s):** -  
**Model(s):** Laparoscopy drape 230 x 320 cm, aperture 25 x 30 cm with incision film per 1 pc, sterile  
Laparoscopy drape 180 x 300 cm with triangular aperture 25 x 21 x 21 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Utility drape  
**Trademark(s):** -  
**Model(s):** Utility drape 75 x 90 cm per 1 pc, sterile  
Utility drape 90 x 120 cm per 1 pc, sterile  
Utility drape 100 x 150 cm per 1 pc, sterile  
Utility drape 150 x 180 cm per 1 pc, sterile  
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**Product name:** Adhesive utility drape  
**Trademark(s):** -  
**Model(s):** Adhesive utility drape 75 x 90 cm per 1 pc, sterile  
Adhesive utility drape 150 x 240 cm per 1 pc, sterile  
Adhesive utility drape 90 x 120 cm per 1 pc, sterile  
Adhesive utility drape 100 x 150 cm per 1 pc, sterile  
Adhesive utility drape 150 x 180 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Utility drape with aperture  
**Trademark(s):** -  
**Model(s):** Utility drape with aperture 75 x 90 cm per 1 pc, sterile  
**Class:** Is



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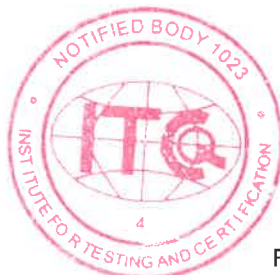
**Product name:** Adhesive utility drape with aperture  
**Trademark(s):** -  
**Model(s):** Adhesive utility drape with aperture 120 x 150 cm per 1 pc, aperture diameter 12 cm, sterile  
**Class:** Is

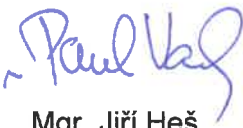
**Product name:** Stockinette  
**Trademark(s):** -  
**Model(s):** Stockinette 36 x 65 cm per 1 pc, sterile (SMALL)  
**Class:** Is

**Product name:** Arm cover  
**Trademark(s):** -  
**Model(s):** Arm cover per 1 pc, sterile  
**Class:** Is

**Product name:** Legging  
**Trademark(s):** -  
**Model(s):** Legging URO/GYN per 2 pcs, sterile  
**Class:** Is

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**Product name:** Arm cover  
**Trademark(s):** -  
**Model(s):** Arm cover 20 x 55 cm per 2 pcs, sterile  
**Class:** Is

**Product name:** Dental drape  
**Trademark(s):** -  
**Model(s):** Dental drape 100 x 160 cm per 1 pc, sterile  
**Class:** Is

**Product name:** Drape SMS  
**Trademark(s):** -  
**Model(s):** Drape SMS 80 x 90 cm per 1 pc, sterile  
Drape SMS 130 x 80 cm per 1 pc, sterile  
**Class:** Is



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**Product name:** Cable/Articulating arm drape  
**Trademark(s):** -  
**Model(s):** Cable/Articulating arm drape per 1 pc sterile  
**Class:** Is

**Product name:** Drape set sterile  
**Trademark(s):** -  
**Model(s):** Set FEMTO LDV Drape set B Ziemer 105554 sterile  
**Class:** Is



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