



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

EU Quality Management System Certificate No. 25 0380 QR/NB

Quality management system of the company

AVEFLOR, a.s.

Budčeves 26, 507 32 Kopidno, Czech Republic

SRN: CZ-MF-000003103

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:

AKUTOL™

Notified Body No. 1023 declares that it has assessed the quality management system of the above manufacturer in accordance with Annex IX, Chapters I and III of Regulation (EU) 2017/745. The quality management system put in place by the manufacturer for the design, manufacture and final inspection of the products concerned 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. 803602930/2025, which is issued together with the present certificate.

Valid from: **2025-09-26**


Valid until: **2030-09-25**

Previous EU certificate No.: -

Previous EU certificate issue date: -

Date of issue: 2025-09-26




Mgr. Jiří Heš
Representative of Notified Body No. 1023



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Annex to EU Quality Management System Certificate No. 25 0380 QR/NB

issued to the manufacturer:

AVEFLOR, a.s.
Budčeves 26, 507 32 Kopidlno, Czech Republic

Manufacturer details:

Manufacturer's company name: **AVEFLOR, a.s.**
Single registration number (SRN): **CZ-MF-000003103**
Registered office address: **Budčeves 26, 507 32 Kopidlno, Czech Republic**
Production site address: **Budčeves 26, 507 32 Kopidlno, Czech Republic**

Details of the authorised representative (if required):

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

Date of issue: 2025-09-26



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issued to the manufacturer:

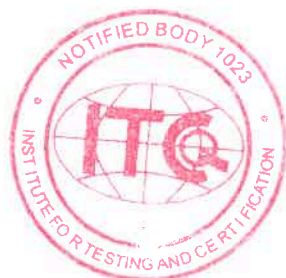
AVEFLOR, a.s.
Budčeves 26, 507 32 Kopidlno, Czech Republic

Product(s):

Product name: AKUTOL™ spray

Trade mark(s):

AKUTOL™ aerosol
AKUTOL™ аэрозоль
AKUTOL™ care
Akutol™ spray
Akutol™ sprej
AKUTOL™ sprej
BUSINESSCARE® Spray plaster
Eureka care® Pleisterspray
FERSTA® Patch ON First Aid
Lidl Pflasterspray/Sprühpflaster
medicare SPRAY PLASTER
Mivolis Sprühpflaster
Osmo Soft Pansement Spray
PharmaLEAD® Plaster Bandage Spray
Plusab Sprayplåster



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PROMERA KLINGGRUPPEN SÂRPLAST
Protection en spray AKUTOL™
RYM® Protect
SÂRPLAST
SÂRPLAST WOUND SPRAY
Sensomed® Pflasterspray
SOS® Pflaster-spray
ST. BENEDIKT Sprühpflaster/ Pflasterspray
ST. CHRISTOPH Sprühpflaster/ Pflasterspray
TENDER CARE
Wound Care
URGO Pansement Spray

Model(s):

Z08 – 60 ml of product in aerosol can
Z29 – 35 ml of product in aerosol can
SZ74 – 75 ml of product in aerosol can

Class:

Ila

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issued to the manufacturer:


AVEFLOR, a.s.
Budčeves 26, 507 32 Kopidlno, Czech Republic

Product name: **AKUTOL™ STOP spray**

Trade mark(s): AKUTOL™ STOP sprej
AKUTOL™ stop spray
AKUTOL™ STOP spray
BLODSTOPP
Blodstopp-spray
BLOODSTOP® Spray
Blood Care
BLOOD STOP
BUSINESSCARE® Blood stop
Eureka care® Wondspray
FERSTA® Blood STOP First Aid
HeltiQ Bloedstop Spray
HEMOFLAM® spray
Lidl Blutstopp-Wundspray
medicare BLEEDING CONTROL SPRAY



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issued to the manufacturer:

AVEFLOR, a.s.
Budčeves 26, 507 32 Kopidlno, Czech Republic

Mivolis Blutstoppspray
Osmo Soft Spray Hémostatique
PharmaLEAD[®] Emostatic Spray
PROMERA KLINGGRUPPEN BLOOD STOP
RYM[®] Stop
Sensomed[®] Blutstopp-Wundspray
SOS[®] Blutstopp-Wundspray
Spray AKUTOL[™] STOP
ST. BENEDIKT Blutstopp-Wundspray
ST. CHRISTOPH Blutstopp-Wundspray
TENDER CARE
URGO Hémostatique Spray

Model(s):

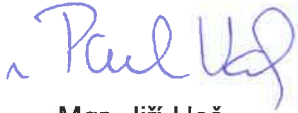
Z07 – 60 ml of product in aerosol can
Z40 – 35 ml of product in aerosol can
SZ58 – 75 ml of product in aerosol can

Class:

Ila



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issued to the manufacturer:

AVEFLOR, a.s.
Budčeves 26, 507 32 Kopidlno, Czech Republic

Product name: AKUTOL™ Burn spray

Trade mark(s): AKUTOL™ Burn spray
AKUTOL™ Sprej na popáleniny
AKUTOL™ Palovammaspray
AKUTOL™ Spray anti brûlures
AKUTOL™ Spray för brännskador
AKUTOL™ Spray na oparzenia
AKUTOL™ Spray para quemaduras
AKUTOL™ spray til brannssår
BUSINESSCARE® Burn Spray
medicare BURN SPRAY
Mivolis Brandwundspray
Osmo Soft Spray Brûlures
PharmaLEAD® Burn Spray
SOS® Brandwundspray
ST. BENEDIKT Brandwundspray
ST. CHRISTOPH Brandwundspray
URGO Brûlures Spray

Model(s): Z35 – 50 ml of product in aerosol can

Class: Ila

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