

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-2010002

Manufacturer:

ACTO GmbH
Büchnerstrasse 11, 38118 Braunschweig GERMANY

Product(s):

1. Medical Device Disinfectant
2. Lubricant Gel
3. Non-Sterile Wound Care Gel
4. Non-Sterile Wound Care Solution
5. Sterile Wound Dressing
6. Sterile Wound Pad

Model(s):

1. Actosed HP Ready, Actoanid Wipes, Actosept AF Tücher, Actosept AF Plus, Acto Oxy Wipes, Acto Oxy Foam
2. Acto Lubricant Gel
- 3-4. Product specifications for Wound Care Gel and Solution are stated in the Design Certificates (2195-MED-2010002-D01, 2195-MED-2010002-D02 and 2195-MED-2010002-D03).
5. Non-Adhesive Wound Dressing, Adhesive Wound Dressing, Foam-Hydrocolloid Wound Dressing, Hydrocolloid Wound Dressing, Hydrocolloid Plus Wound Dressing, Hydrocolloid Thin Wound Dressing, Plus Foam Wound Dressing, Plus Foam Thin Wound Dressing, Plus Foam Adhesive Wound Dressing, Plus Hydrocolloid Wound Dressing
6. Wound Pad, Wound Pad- Adhesive, Wound Pad- Transparent Adhesive

Reference Report No:

MM0826-P001-R01, MM0826-P001-R02, MM0826-P001-R03, MM0826-P001-R04, MM0826-P002-R01, MM0826-P004-R01, MM0826-P004-R02, MM0826-P004-R03, MM0826-P004-R04, MM0826-P004-R05, MM0826-P004-R06, MM0826-P004-R07, MM0826-P004-R08, MM0826-P004-R09, MM0826-P004-R10, MM0826-P004-R11, MM0826-P004-R12

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2020-04-09
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Rukiye BALKAN
Deputy General Manager