

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC,
Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company
PRISMAN GmbH

Otto-Hahn-Ring 6-18, 64653 Lorsch, Germany

Certified location:

Otto-Hahn-Ring 6-18, 64653 Lorsch, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50681-Z5-00, the decision dated 2019-05-28 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-05-30 to 2024-05-26

Registration No.: 50681-16-04

Ruth Delbeck-Bayer



Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-05-28
Notified Body ID-number: 0124

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
ZLG-BS-295.10.02
www.zlg.de

EC CERTIFICATE

for the Quality Assurance System



**according the Directive 93/42/EEC,
Annex V**

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Annex to the EC Certificate No. 50681-16-04

Valid from 2019-05-30 to 2024-05-26

Revision status of the annex: 0 dated 2019-05-28

Devices/device categories included in the certificate:

Klasse II b:

MD0108

Instrument disinfection

- Instrument Disinfection BASIS conc., ID 200 conc. (incl. Zyme)
- Instrument Disinfection FINISH, ID 710
- Instrument Disinfection conc., ID 300 conc.
- Instrument Disinfection PLUS conc., ID 400 conc.
- Instrument Disinfection POW(D)ER PLUS conc., IDP 400 conc.
- Instrument Disinfection POW(D)ER HIGH conc., IDP 700 conc.
- Instrument Disinfection Cleaner SOLIDSEPT conc., IC 270 conc.
- Instrument Disinfection PREMIUM PLUS., ID 470 conc.
- Instrument Disinfection PREMIUM HIGH conc., ID 770 conc.
- Instrument Disinfection VIREX BASIC conc., ID 200 conc.
- Instrument Disinfection VIREX HIGH conc., ID 700 conc.

Drill Bath

- Drill Bath PLUS, DB 400
- Drill Bath HIGH, DB 700
- Drill Bath, DB 200
- Drill Bath VIREX, DB 700

Surface Disinfection

- Surface Disinfection VIREX FORTE, SD 710 including Disinfection Wipes
- Surface Disinfection VIREX BASIC conc., SD 200 conc.
- Surface Disinfection VIREX PLUS conc., SD 400 conc.
- Surface Disinfection VIREX HIGH conc., SD 700 conc.

Rapid Surface Disinfection

- Rapid Surface Disinfection BIO, RSD 410 including Disinfection Wipes
- Rapid Surface Disinfection MAX, RSD 500 including Disinfection Wipes
- Rapid Surface Disinfection MAX, RSD 600 including Disinfection Wipes
- Rapid Surface Disinfection MED, RSD 700 including Disinfection Wipes



Ruth Delbeck-Bayer

DEKRA Certification GmbH, Stuttgart, 2019-05-28

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Valid from 2019-05-30 to 2024-05-26

Revision status of the annex: 0 dated 2019-05-28

Devices/device categories included in the certificate:

Class II a:

MD0108

Suction System Disinfection

- Suction System Disinfection conc., SS 400 conc.

Surface Disinfection

- Surface Disinfection BASIS conc., SD 200 conc.
- Surface Disinfection conc., SD 300 conc.
- Surface Disinfection PROTECT conc., SD 420 conc.
- Surface Disinfection PREMIUM conc., SD 240 conc.
- Surface Disinfection PREMIUM POWDER conc., SDP 800 conc.
- Surface Disinfection RAPID FOAM PLUS, RFD 440 including Disinfection Wipes
- Surface Disinfection RAPID FOAM HIGH, RFD 740 including Disinfection Wipes

Impression Disinfection

- Impression Disinfection PLUS, IM 400
- Impression Disinfection, IM 200
- Impression Disinfection, IM 250

Spittoon Disinfection

- Spittoon Disinfection SPITTOON, SP 400
- Mundspülbeckendesinfektion NANO, SPN 700

Rapid Surface Disinfection

- Spittoon Disinfection, RSD 400 including Disinfection Wipes

MD0402

Etching Gel

- Etching Gel

Primer

- Silanization Liquid SILANO



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