

**Produktdokumentation
EG-Konformitätserklärung
Absauganlagendesinfektion
Konzentrat SS400 conc.**

Zertifikats-Registrier-Nr. 50681-17-05
Gültig bis 26.05.2024

PRISMAN GmbH
Otto-Hahn-Ring 6-18
D-64653 Lorsch
Germany

Fon: +49(0)6251-866 980-0
Fax: +49(0)6251-866 980-77
Fax: +49(0)6251-866 980-78
Auftragsabwicklung
e-mail: info@prisman.de
http://www.prisman.com

**Wir, die PRISMAN GmbH
Otto-Hahn-Ring 6-18
64653 Lorsch**

erklären in alleiniger Verantwortung, dass es sich bei dem Produkt

**Absauganlagendesinfektion Konzentrat
SS400 conc.**

(inkl. den Varianten KS-x [x= A-Z])

**Artikelnummer / Rezepturschlüssel: 115
GMDN: 47631**

Sowie den identischen Produkten gemäß Anhang I bis XIV.

gemäß den Bestimmungen der Richtlinie 93/42/EWG des Rates vom 14.6.1993 über Medizinprodukte (geändert durch 2007/47/EG), Anhang IX, Regel 15 um ein Medizinprodukt der Klasse IIa handelt.

Das Konformitätsbewertungsverfahren entspricht nach 93/42/EWG, Artikel 11, Absatz 2 dem Anhang V und VII der 93/42/EWG Richtlinie.

Die anwendbaren grundlegenden Anforderungen nach Anhang I, 93/42/EWG werden erfüllt.

Das Produkt entspricht den einschlägigen Bestimmungen der Richtlinie 93/42/EWG.

Lorsch, 15.01.2021

Ort, Datum

CE 0124

Benannte Stelle:
DEKRA Certification GmbH (0124)
Handwerkstrasse 15
D-70565 Stuttgart
Änd.Stand: 2021-01
Rev.13


Dr. Maria Ahrens / QMB

Qualitätsmanagement
Quality Assurance:
EN ISO 9001
EN ISO 13485
Annex V, Directive 93/42/EEC
Annex II, Directive 93/42/EEC

Herstellerelaubnis Nr.
Manufacturing Authorisation No.
DE-RPDA-001-V-28-1-0

GMP, Directive 2001/83/EC

Es gelten unsere AGB's in
der jeweils aktuellen
Fassung auf der Rückseite

HRB 93716
Amtsgericht Darmstadt

Geschäftsführer
CEO:
Stephan W. Metzger

USt-IdNr./
VAT-No. DE 812526190
Steuer-Nr. 00724100808
Zoll-Nr. 4797930

Bankverbindungen
Bank accounts:

Volksbank
Kreis Bergstraße
BLZ 508 900 00
Kto.-Nr. 30290305
IBAN
DE48 5089 0000 0030 2903 05
S.W.I.F.T./BIC-CODE:
GENODEF1VBD

Sparkasse
Starkenburg
BLZ 509 514 69
Kto.-Nr. 3032439
IBAN
DE08 5095 1469 0003 0324 39
S.W.I.F.T./BIC-CODE:
HELADEF1HEP

Table 2: Devices covered by this letter and for which the NB (0124) is NOT responsible but a subject for appropriate surveillance of the corresponding devices under the certification scope of the EN ISO 13485 certificate:

Product or product group identification acc. to MDD -certificate	MDD Device classification	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate and Certificate Annex No. with revision
Prophylaxepulver/ Prohylaxe Powder PROPHY FRESH, PROPHY TOP, PROPHY SOFT, PROPHY PERIO PLUS, PROPHY SOFT PERIO	I	Prophylaxepulver/ Prohylaxe Powder PROPHY FRESH, PROPHY TOP, PROPHY SOFT,	MDR Application ID: Change Notification ÄM- 50681-CN24-01 dd. 2024- 03-06 to A22051578

PRISMAN GmbH • Otto-Hahn-Ring 6-18 • D-64653 Lorsch • Germany

PRISMAN GmbH
Otto-Hahn-Ring 6-18
D-64653 Lorsch • Germany
Tel.: +49 (0) 6251 866 980-0
Fax: +49 (0) 6251 866 980-77

info@prisman.de
www.prisman.de

Manufacturer's declaration to extend the validity of the declaration of conformity.

SRN DE-MF-000009900

To whom it may concern,

PRISMAN GmbH has made use of the possibility of extending the validity described in more detail in the amendment to Regulation (EU) 2017/745 by Regulation (EU) 2023/607 and has received the necessary letter of confirmation (50681-Col-00, Rev.0) from DEKRA Certification GmbH (CE 0124) as Notified Body.

For the medical devices covered by the letter of confirmation in accordance with the EC certificate pursuant to Directive 93/42/EEC Annex II without Section (4) Appendix No. 50681-17-05 and No. 50681-16-04, valid until 2024-05-26, the following validity extensions apply with immediate effect:

- **31 December 2028** for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- **31 December 2028** for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as reusable surgical instruments)

The letter of confirmation covers all products listed in the annex.

Kind regards

Dr. Simone Sartorius-Neef, QMR

Annex to Notified Body Confirmation Letter 50681-CoL-00, Rev. 0

Table 1: Devices covered by this letter and for which the notified body DEKRA Certification GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Annex MDD:

Product or product group identification acc. to MDD -certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision
Instrumentendesinfektion BASIS Konz., ID 200 conc. (inkl. ZYME)/ Instrument Disinfection BASIS., ID 200 conc. (incl.Zyme)	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion FINISH, ID 710/ Instrument Disinfection FINISH, ID 710	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER PLUS Konz., IDP 400 conc./ Instrument Disinfection POW(D)ER PLUS conc., IDP 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion POW(D)ER HIGH Konz., IDP 700 conc./ Instrument Disinfection POW(D)ER HIGH conc., IDP 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumenten Desinfektionsreiniger SOLIDSEPT Konz., IC 270 conc./ Instrument Disinfection Cleaner SOLISEPT conc. , IC 270 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM PLUS Konz.,ID 470/ Instrument Disinfection PREMIUM PLUS., ID 470 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion PREMIUM HIGH Konz., ID 770 conc./ Instrument Disinfection PREMIUM HIGH conc., ID770 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX BASIC Konz., ID 200 conc./ Instrument Disinfection VIREX BASIC conc., ID 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Instrumentendesinfektion VIREX HIGH Konz., ID 700 conc./ Instrument Disinfection VIREX HIGH conc., ID 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad PLUS, DB 400/ Dril Bath PLUS, DB 400	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad HIGH, DB 700/ Drill Bath HIGH, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Bohrerbad VIREX, DB 700/ Drill Bath VIREX, DB 700	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX FORTE SD 710 inkl.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28

Desinfektionstücher/ Surfacec Disinfection VIREX FORTE, SD 710 including Disinfection Wipes		
Flächendesinfektion VIREX BASIC Konz., SD 200 conc./ Surfacec Disinfection VIREX BASIC conc., SD 200 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX PLUS Konz., SD 400 conc./ Surfacec Disinfection VIREX PLUS conc., SD 400 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Flächendesinfektion VIREX HIGH Konz., SD 700 conc./ Surfacec Disinfection VIREX HIGH conc., SD 700 conc.	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- Wischdesinfektion BIO, RSD 410 inkl. Desinfektionstücher/ Rapis Surface Disinfection BIO, RSD 410 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 500 inklusive Desinfektionstücher/ Rapis Surface Disinfection MAX, RSD 500 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MAX, RSD 600 inklusive Desinfektionstüchern/ Rapis Surface Disinfection MAX RSD 600 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Sprüh- und Wischdesinfektion MED, RSD 700 inklusive Desinfektionstücher/ Rapis Surface Disinfection MED, RSD 700 including Disinfection Wipes	IIb	EU-certificate acc. to Anx. II excl. section 4 MDDNo.: 50681-16-04, valid until 2024-05-26 with Annex: 0 dd. 2019-05-28
Absauganlagendesinfektio n Konz., SS 400 conc./ Suction System Disinfection conc., SS 400 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion Konz., SD 300 conc./ Surface Disinfection conc., SD 300 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion PROTECT Konz., SD 420/ Surface Disinfection PROTECT conc., SD 420 conc.	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion RAPID FOAM PLUS, RFD	IIa	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02

440 inkl. Desinfektionstücher/ Surface Disinfection RAPID FOAM PLUS, RFD 400 including Disinfection Wipes		
Flächendesinfektion RAPID FOAM HIGH, RFD 740 inklusive Desinfektionstücher/ Surface Disinfection RAPID FOAM HIGH, RFD 740 including Disinfection Wipes	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
AbformdesinfektionPLUS, IM 400/ Impression Disinfection PLUS, IM 400	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Abformdesinfektion, IM 200/ Impression Disinfection, IM 200	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfek- tion SPITTOON, SP 400/ Spittoon Disinfection SPITTOON, SP 400	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Mundspülbeckendesinfek- tion NANO, SPN 700/ Spittoon Disinfection NANO, SPN 700	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
SprühWischdesinfektion, RSD 400 inklusive Desinfektionstücher/ Spittoon Disinfection, RSD 400 including Disinfection Wipes	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Ätzelgel/ Etching Gel	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Silanisierungsliquid SILANO/ Silanization Liquid SILANO	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02
Flächendesinfektion BASIC Konz., SD 200 conc./ Surface Disinfection BASIC conc., SD 200 conc.	Ila	EU-certificate acc. to Anx. V MDDNo.: 50681-17-05, valid until 2024-05-26 with Annex: 1 dd. 2019-12-02



Anhang XIV.VI EU- Konformitätserklärung
Annex XIV.VI for EU Declaration of Conformity

Rev.:00

Stand |State:2024-10

erstellt/geändert|SO

Created/changed:

Für den Kunden |KaVo

for customer:

Rezepturschlüssel|115

Recipe Key:

Basis UDI-DI |++EPRM115DJ

Basic UDI-DI:

Artikelnummer Kunde Item number Customer	Artikelbezeichnung Kunde Item description customer	Gebinde- größe Packaging size	Artikelnummer Lieferant Supplier item number	Artikelbezeichnung Supplier item description (DE)	Artikelbezeichnung Supplier item description (EN)	KS-Type KS-Type	UDI-DI
1.015.6145	DEKASEPTOL Gel	60 L	115D0060L-KV01	Absauganlagendesinfektion Konz. SS400 conc.	Suction System Disinfection conc. SS 400 conc.	KS-D	04064797030608
1.015.4800	DEKASEPTOL Gel	1 L	115D01000-KV01	Absauganlagendesinfektion Konz. SS400 conc.	Suction System Disinfection conc. SS 400 conc.	KS-D	04064797030585
1.015.4805	DEKASEPTOL Gel	5 L	115D05000-KV01	Absauganlagendesinfektion Konz. SS400 conc.	Suction System Disinfection conc. SS 400 conc.	KS-D	04064797030592