

**Product documentation**  
**EC-Declaration of Conformity**  
**Prophylaxis powder**

Valid until **2022-05-29**

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

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

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

Declare under our sole responsibility that the following product(s)

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

GMP, Directive 2001/83/EC

**Prophylaxis powder PROPHY TOP /  
PROPHY SOFT / PROPHY PERIO PLUS /  
PROPHY SOFT PERIO**  
**(including various types KS-x [x= A-Z])**

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

HRB 93716  
Amtsgericht Darmstadt

**Item number / Recipe key: 436 / 437 / 438 / 439**

Geschäftsführer  
CEO:  
Stephan W. Metzger

**As well as the identical products listed in Annex I – XV**

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

is according to the provisions of the Directive 93/42/CEE of the Council as of 06-14-1993 regarding medical devices, Annex IX, rule 5 a medical device of class I.

The conformity assessment procedure corresponds to the provisions of annex VII of the Directive 93/42/CEE according to article 11, paragraph 5 of the Directive 93/42/CEE. The basic requirements as of Annex I of the Directive 93/42/CEE are met. The product corresponds to the requirements of the directive 93/42/CEE.

Bankverbindungen  
Bank accounts:

Lorsch, **2022-03-25**

Place, Date



**Dr. Maria Ahrens**  
**QMR**

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



**Anhang XV Konformitätserklärung**  
**Annex XV for EC-Declaration of Conformity**

Rev.: 00  
 Stand | State: 2022-03  
 erstellt/geändert: SO  
 Created/changed:  
 Rezepturschlüssel: 436 | 437 | 438 | 439  
 Recipe Key:

Artikelnummer Kunde Item number Customer	Artikelbezeichnung Kunde Item description customer	Gebinde- größe Packaging	Artikelnummer Lieferant Supplier item number	Artikelbezeichnung Supplier item description (DE)	Artikelbezeichnung Supplier item description (EN)	KS/KV-Typ KS/KV Type
.08020870	Prophylaxis Powder SOFT+	4x250g	436A4x250-WH01	Prophylaxepulver PROPHY TOP	Prophylaxis powder PROPHY TOP	KS-A
.08020890	Prophylaxis Powder SENSITIVE+	2x160g	439-2x160-WH01	Prophylaxepulver PROPHY SOFT PERIO	Prophylaxis powder PROPHY SOFT PERIO	