

Product documentation
EC-Declaration of Conformity
Prophylaxis powder

Valid until **2024-05-26**

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

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

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

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

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

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.

Lorsch, **2022-05-25**

Place, Date



Dr. Maria Ahrens
QMR

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

Herstellerlaubnis 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

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