

Nika Medical Produkte GmbH · Breiten Dyk 25a · D-47803 Krefeld



zertifiziert
seit Mai 2016

D-47803 Krefeld · Breiten Dyk 25a
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DICHIARAZIONE DI CONFORMITA'CE

Si dichiara, sotto la propria responsabilità, che il dispositivo sotto reportato, è fabbricato dalla NIKA MEDICAL PRODUKTE GMBH e soddisfa tutte le disposizioni applicabili dalla Direttiva 93/42/CEE (recepita con D. Lgs n° 46 del 24.02.1997) sui Dispositivi Medici.

Nome prodotto: **ZINCABAND "E"**

Descrizione: banda elastica impregnata di crema all'ossido di zinco

Classe di appartenenza: CLASSE I

Distributore: **FRA PRODUCTION SPA** - Via delle Poste n. 16 - 14010 Dusino San Michele (AT)

Secondo 2007/47 EG


Krefeld, addi 29.09.2017



NIKA®
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EC-Declaration of Conformity

within the meaning of

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

The product is a medical device of class I.

Product: ZINCABAND "E"

Variants: elastic bandage soaked in zinc oxide cream

The product is designed and manufactured according to Directive 93/42/EEC under sole responsibility of:

Manufacturer: NIKA Medical Produkte GmbH
Breiten Dyk 25a
47803 Krefeld

Distributor: FRA PRODUCTION SPA
VIA DELLE POSTE, 16
14010 DUSINO SAN MICHELE (AT)

The technical documentation with risk analysis is completely available. This declaration is valid for at least 1 year after signing.

The product meets the essential requirements according to **Annex I** of the Directive 93/42/EEC. The instructions concerning the product are available. The conformity assessment procedure was carried out in accordance with **Annex VII** of Directive 93/42/EEC.

Krefeld, 28.11.2019

Place, Date



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Managing director