

To our business partners


Baden, October 2023

Dear Sir or Madam,

The Medical Device Directive 93/42/EEC (MDD) and the corresponding national legal regulations were replaced in May 2021 by the EU Regulation 2017/745 (Medical Device Regulation - MDR for short). Currently, the transitional provisions according to MDR Article 120 apply to our medical devices. All our medical devices have declarations of conformity which were issued before 26.05.2021. MDR Article 120 Paragraph 3 applies, which allows the products to be made available in the known form until 31 December 2028.

Of course, we are already working on making our medical devices available in accordance with the new regulation. As soon as we receive the new declarations of conformity from the Notified Body, we will publish them on our homepage.

With kind regards



Ing. Mag. Eva Bano
BANO Healthcare GmbH

KONFORMITÄTSERKLÄRUNG

DECLARATION OF CONFORMITY

Wir erklären in alleiniger Verantwortung, dass die unten beschriebenen Produkte in der gelieferten Ausführung den Anforderungen der Richtlinie 93/42/EWG und des österreichischen Medizinproduktegesetzes BGBl. 657/1996 i.d.g.F. entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen.

We declare under sole responsibility that the products described below as delivered are in compliance with directive 93/42/EEC and the Austrian medical-device-law BGBl. 657/1996. The products are CE marked.

Produkt/Product: **SILVERIN®**

Varianten mit Artikelnummer/Type with article number:

1304630	SILBERNITRAT-KALIUMNITRAT ÄTZSTÄBCHEN 115 MM STARR 10 STÜCK
1304654	SILBERNITRAT-KALIUMNITRAT ÄTZSTÄBCHEN 115 MM ELASTISCH 10 STÜCK
1304647	SILBERNITRAT-KALIUMNITRAT ÄTZSTÄBCHEN 200 MM STARR 10 STÜCK
1304678	SILBERNITRAT-KALIUMNITRAT ÄTZSTÄBCHEN 200 MM ELASTISCH 10 STÜCK
1304117	SILVERIN® STICKS 50% 115 MM STARR 10 STÜCK
1304124	SILVERIN® STICKS 50% 115 MM ELASTISCH 10 STÜCK
1304131	SILVERIN® STICKS 50% 200 MM STARR 10 STÜCK
1304148	SILVERIN® STICKS 50% 200 MM ELASTISCH 10 STÜCK
1304155	SILVERIN® STICKS 50% 115 MM STARR 100 STÜCK
1304162	SILVERIN® STICKS 50% 115 MM ELASTISCH 100 STÜCK
1304179	SILVERIN® STICKS 50% 200 MM STARR 100 STÜCK
1304216	SILVERIN® STICKS 75% 115 MM STARR 100 STÜCK
1304223	SILVERIN® STICKS 75% 115 MM ELASTISCH 100 STÜCK
1304230	SILVERIN® STICKS 75% 200 MM STARR 100 STÜCK
1304277	SILVERIN® STICKS 75% 200 MM STARR 10 STÜCK

Klassifizierung/Classification: Klasse 1 /Class I

Angewandte harmonisierte Normen/Used harmonised norms:

EN ISO 13485:2016
EN ISO 14971:2020
EN ISO 15223-1:2016
EN ISO 10993
EN 1041:2013
IEC 62366-1:2015

Gekennzeichnet mit/marked:



Hersteller/manufacturer: BANO Healthcare GmbH



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Baden, 27.04.2021

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Geschäftsführung/Managing director