

Shanghai Dochem Industries Co., Ltd.

EU DECLARATION OF CONFORMITY

Manufacturers Name: Shanghai Dochem Industries Co. ,Ltd.
Suite E2014, 2nd Floor, No. 3558, Zhenbei Road, Putuo District,
Manufacturer Address: Shanghai, China.
Manufacturer SRN: CN-MF-000014350
Authorized European Representative Name: MedNet EC-Rep GmbH
Authorized European Representative Address: Borkstrasse 10, 48163 Muenster, Germany
Authorized European Representative SRN: DE-AR-000000002

We declare under our sole responsibility that:

Name of the Device (s): Micro Applicator
Product code: See below annex 1
classification: Class I According to annex VIII of the Regulation EU 2017/745 (MDR)
Basic UDI-DI: 69523679010003YD

Conformity assessment procedure: EU conformity declaration according to Annex IV of the Regulation EU 2017/745(MDR).



Shanghai Dochem Industries Co.,Ltd. applies the following,
ISO 13485:2016
EN ISO 14971:2019
EN ISO 15233:2021
EN ISO 20417:2021
EN 62366-1:2015/A1:2020
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2021

This declaration of conformity is issued under the sole responsibility of Shanghai Dochem Industries Co., Ltd.

We hereby declare that the medical device specified above meet the provision of the Regulation EU 2017/745(MDR).

The declaration is valid in connection with the "final inspection report" of the device.

Shanghai, 2024-02

Place, date /



Hanbin Dou, General Manager

Name and function

Shanghai Dochem Industries Co., Ltd.

Attachment of the Declaration of Conformity: **Annex 1**

PRODUCT NAME: Micro Applicator

| Reference number | Description | Packing |
|------------------|---------------------------------------|---|
| 1A6541 | 2.0mm, Regular | 100pcs/bucket, 10buckets/box, 20buckets/ctn |
| 1A6542 | 1.5mm, Fine | 100pcs/bucket, 10buckets/box, 20buckets/ctn |
| 1A6543 | 1.0mm, Superfine | 100pcs/bucket, 10buckets/box, 20buckets/ctn |
| 1A6544 | extra-thin and extended | 100pcs/bucket, 10buckets/box, 20buckets/ctn |
| 1A6541-R | 2.0mm, Regular; round bucket | 100pcs/bucket, 4buckets/box, 40boxes/ctn |
| 1A6542-R | 1.5mm, Fine; round bucket | 100pcs/bucket, 4buckets/box, 40boxes/ctn |
| 1A6543-R | 1.0mm, Superfine; round bucket | 100pcs/bucket, 4buckets/box, 40boxes/ctn |
| 1A6544-R | extra-thin and extended; round bucket | 100pcs/bucket, 4buckets/box, 40boxes/ctn |
| 1A6548 | regular, 2.0mm (4buckets/box) | 100pcs/bucket, 4buckets/box, 40boxes/ctn |