

EU DECLARATION OF CONFORMITY

**Manufacturers Name:** Shanghai Dochem Industries Co. ,Ltd.  
**Manufacturer Address:** Suite E2014, 2nd Floor, No. 3558, Zhenbei Road, Putuo District, 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):** Dental cotton rolls  
**Product code:** See below annex 1  
**classification:** Class I According to annex VIII of the Regulation EU 2017/745 (MDR)  
**Basic UDI-DI:** 69523679010007YM

**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 15223:2021
- 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
- EN 14079:2003

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

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

PRODUCT NAME: Dental cotton rolls

Reference number	Description	Pcs/bag
1A0001	0.8x3.8cm	1000
1A0002	0.8x3.8cm	2000
1A0003	0.8x3.8cm	750
1A0011	1.0x3.8cm	1000
1A0012	1.0x3.8cm	2000
1A0013	1.0x3.8cm	600
1A0015	1.0x3.8cm	500
1A0021	1.2x3.8cm	1000
1A0000	0.8x3.8cm	2000
1A0010	1.0x3.8cm	2000
1A0014	1.0x3.8cm	600
1A0020	1.2x3.8cm	2000