

## EU DECLARATION OF CONFORMITY

Manufacturers Name: Shanghai Dochem Industries Co.,Ltd.  
Manufacturer Address: Suite E2014, 2nd Floor, No. 3558, Zhenbei Road, Putuo District, 200060 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): Impression Tray  
Product code: See page 2  
Classification: Class I, according to rule 1, Annex VIII of Regulation EU 2017/745(MDR)  
Basic UDI-DI: 69523679010015YL

Conformity assessment procedure: EU conformity declaration according to Annexes II and III of EU 2017/745 (MDR).



Shanghai Dochem Industries Co., Ltd. applies the following harmonized standards in according to the Regulation EU 2017/745 (MDR) and to which this declaration relates is in conformity with the provisions and requirements of MEDDEV 2.7/1 rev 4、MEDDEV 2.12/1 rev 8:

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 10993-10:2013

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).



Hanbin Dou , General Manager

Name and function

Attachment of the Declaration of Conformity:

PRODUCT NAME

Disposable impression trays are used to carry, confine and control impression material for making impression of patients' teeth.

REF	Size	Product description
1A5910	Large	Upper
1A5911	Large	Lower
1A5912	Medium	Upper
1A5913	Medium	Lower
1A5914	Small	Upper
1A5915	Small	Lower
1A5916	-	Upper Right/Lower Left
1A5917	-	Upper Left/Lower Right
1A5918	-	Anterior