

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): LUER-LOCK IRRIGATION SYRINGES

Product code: See below annex 1
classification: Class I According to annex VIII of the Regulation EU 2017/745 (MDR)
Basic UDI-DI: 69523679020004YS

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 62366-1:2015/A1:2020
EN ISO 14971:2019
EN ISO 20417:2021
EN ISO 15223:2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10:2023

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.



Hanbin Dou, General Manager
Name and function

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

PRODUCT NAME: LUER-LOCK IRRIGATION SYRINGES

Product code	Product name	Specification
1A2040	LUER-LOCK IRRIGATION SYRINGES	1.2ml
1A2041	LUER-LOCK IRRIGATION SYRINGES	3ml
1A2042	LUER-LOCK IRRIGATION SYRINGES	5ml
1A2043	LUER-LOCK IRRIGATION SYRINGES	10ml
1A2044	LUER-LOCK IRRIGATION SYRINGES	6ml
1A2045	LUER-LOCK IRRIGATION SYRINGES	12ml
1A2041-CR	IrriGance™ Color Syringe 21422	3ml, red plunger
1A2041-CW	IrriGance™ Color Syringe 21423	3ml, white plunger
1A2041-CB	IrriGance™ Color Syringe 21424	3ml, black plunger
1A2042-CR	IrriGance™ Color Syringe 21425	5ml, red plunger
1A2042-CW	IrriGance™ Color Syringe 21426	5ml, white plunger
1A2042-CB	IrriGance™ Color Syringe 21427	5ml, black plunger
1A2043-CR	IrriGance™ Color Syringe 21428	10ml, red plunger
1A2043-CW	IrriGance™ Color Syringe 21429	10ml, white plunger
1A2043-CB	IrriGance™ Color Syringe 21430	10ml, black plunger
1A2042-MS	IrriGance™ Color Syringe 21431	5ml assorted: red, white, black