

Shanghai ISO Medical Products Co., Ltd. CE Technical Documentation Adhesive Dressing With Pad Manufacturing site activities	Document No.	CE/04-01(A)
	Version	A.6
	Effective Date	2024.04.07

Shanghai ISO Medical Products Co., Ltd.

999 Liu Chen Rd, Pudong New Area Shanghai, P.R. China

EC Declaration of Conformity

For the following products:

Adhesive Dressing with Pad

(Product Name)

Non-woven Island Dressing: width:0.5cm~30cm; length:3cm~50cm;

(Model Designation)

is hereinafter confirmed to comply with:

1.the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

2.REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

Applicable standards are:

EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 14644-1:2015, EN 17141:2020, ASTM D3654/D3654M-06(2019), ASTM D3330/D3330M-04(2018), EN ISO 14971:2019, EN ISO 10993-7:2008, EN 13726-4:2003, EN 13726-2:2002, EN 13726-3:2003, EN ISO 11737-1:2018, EN ISO 11737-2:2020, EN ISO 11135:2014, IEC 62366-1:2015/AMD 1:2020; EN ISO 10993-12:2021

Classification:

Ila

Conformity Assessment Route:

Annex V of Medical Device Directive

Notified Body:

DNV Product Assurance AS (NB No. 2460)

Veritasveien 1,1363 Høvik, Norway

EC Certificate No.: 10000308503-PA-NA-CHN

Issue date: 2020-11-25

Expiry date: 2024-05-27

Notified Body Confirmation Letter Reference: C680617

Issue date: 2024-03-26

Expiry date: 2028-12-31

The following European Authorized Representative is stated to the declaration:

Company Name: Lotus NL B.V.

Company Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Shanghai ISO Medical Products Co., Ltd.

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Company Address: 999 LiuChen Rd. Pudong New Area Shanghai,P.R.China.

Louise Yi

(Legal Signature)

Registration Manager

(Position/title)

2024-04-07

(Date)