

Certificate CN20/42555

The management system of

Ningbo HSCC Medical Technology Co., Ltd.

No. 56 Luoming South Road, Houfuan, Mingxing Village, Guanhaiwei Town, Cixi City, Zhejiang Province, 315316, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

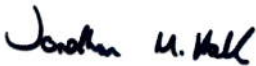
EN ISO 13485:2016

For the following activities

Manufacture of Vomit bag, Medical Face Shield, Medical Isolation Goggles, Sharps Container and Respiratory Exerciser



This certificate is valid from 19 November 2023 until 18 November 2026 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19 November 2020



Authorised by

Jonathan Hall

Global Head - Certification Services

SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

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Ningbo HSCC Medical Technology Co. Ltd.

No. 56 Luoming South Road, Houfuan, Mingxing Village, Guanhaiwei Town, Cixi City, Zhejiang Province, 315316, P.R. China

Declaration of Conformity

Manufacturer:

Name: Ningbo HSCC Medical Technology Co. Ltd.

Address: No. 56 Luoming South Road, Houfuan, Mingxing Village, Guanhaiwei Town, Cixi City, Zhejiang Province, 315316, P.R. China

European Representative:

Name: Eunitor GmbH

Address: Kennedydamm, 5 40476 Düsseldorf, Germany

Product Name: Sharp Container

Model: 0.7L, 0.8L, 1L, 1.5L, 2L, 3L, 4L, 4.6L, 5L, 6L, 8L, 10L, 23L

Classification: Class I

Rule: MDR (EU) 2017/745, Annex VIII, CHAPTER III, Rule 1

Intended use: For the safe collection and temporary storage of medical sharp instruments, designed to effectively prevent sharp instrument injuries and cross-infection.

Conformity Assessment Route: MDR (EU) 2017/745, Annex IX, Chapter I

We herewith declare that the above products comply with all applicable requirements of the European Union Medical Device Regulation (EU 2017/745, MDR). Products comply with the following harmonized standards and specific regulatory requirements. All supporting documentation is retained at the premises of the manufacturer.

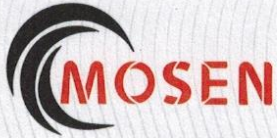
Standards: EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 23907:2019

Place, Date of Issue: Cixi, 2025-01-01

Name/Signature: Wang Leiping

Position: General Manager





CERTIFICATE

of Conformity

Reference No.: MOS202108311262S

Applicant : NINGBO HSCC MEDICAL TECHNOLOGY CO., LTD

Address : No.56 LuoMing South Road, houfu'an, Mingxing village, Guanhaiwei town, Cixi City, Ningbo City, Zhejiang Province, China

Product : Medical Sharps Container

Model(s) : 0.1L,0.2L,0.3L,0.5L,0.7L,0.8L,1L,1.5L,1.7L,2L,2.4L,3L,3.6L,4L,4.6L,5L,6L,7L,7.6L,8L,10L,12L,13.8L,15L,22.7L,23L,30.3L,31L,38L,44L,46L,64L,1quart,2quart,5.4quart,1gallon,3gallon,4gallon,6gallon,8gallon,10gallon,12gallon,17gallon

The submitted products have been tested by us with the listed standards and found in compliance with the following European Directives:

The General Product Safety Directive 2001/95/EC

EN ISO 23907-1:2019

The tests were performed in normal operation mode. The test results apply only to the particular sample tested and to the specific tests carried out. This certificate applies specifically to the sample investigated in our test reference number only.

The CE markings as shown below can be affixed on the product after preparation of necessary technical documentation.

Other relevant Directives have to be observed.



Mosen Detection Technology Co., Ltd.

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