

3 Declaration of Conformity

Manufacturer:

Name: Danyang Sunmed Healthcare Corp.

Address: No.3 Bei Er Huan, Dangyang City, Jiangsu Province 212300, P.R. China

SRN: CN-MF-000013734

European Representative:

Name: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

SRN: DE-AR-000000001

Importer: XD Connects B.V.

Address: Lange Kleiweg 6-28, 2288 GK Rijswijk, The Netherlands

Product Name: CPR mask

Model/size: SH-5500, SH-5501

Basic UDI-DI: 697456746000035Y

Intended use: Prevent the first aider from infection while taking artificial respiration.

Risk Class of the Device: The medical device has been assigned to class I, rule 1 according to ANNEX VIII, Medical Device REGULATION (EU) 2017/745.

GMDN code: 61326

Conformity Assessment Route: Annex II, Annex III of EU 2017/745

We herewith declare that the abovementioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promises of the manufacturer.

Danyang Sunmed Healthcare Corp. is exclusively responsible for the declaration of conformity.

DIRECTIVES

General applicable directives:

EN ISO 14971:2019, EN ISO15223-1:2021, EN ISO10993-1, EN ISO 10993-5, EN ISO 10993-10

Signature of issue person:



Position: General Manager

Name: Sun Weiliang

Date: 2026-5-22

Place: Dangyang