

# 01 EU Declaration of Conformity

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Name: Taizhou Runmei Sanitary Products Co., Ltd.  
 Add: South Factory of F2, Building 4, No80 Xiaqi Road, Suchen Town, Hailing District, 225319 Taizhou, Jiangsu Province, China

Trade mark: /

SRN: CN-MF-000040341

European Representative: Name: MedPath GmbH  
 Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

Product Name: Sterile Isopropyl Alcohol Pad

Trade Name: N.A.

Product REF: AP001, AP002, AP003, AP004, AP005, AP006, AP007  
 AC001, AC002, AC003, AC004, AC005, AC006, AC007

Basic UDI-DI: 697624465AP3G(without 2% chlorhexidine)  
 697624465AC2N(with 2% chlorhexidine)

EMDN Code: V0799

Classification Acc. to MDR Ax. VIII: Class Is, Rule 1

Applied Standard & Common Specification:

EN ISO 13485:2016/A11:2021	EN ISO 14971:2019/A11:2021	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2023	EN ISO 10993-12:2021
EN ISO 10993-23:2021	EN ISO 20417: 2021	EN ISO 15223-1:2021
EN 62366-1: 2015+A1:2020	EN ISO 11137-1:2015/A2:2019	EN ISO 11137-2:2015/A1:2023
EN ISO 11137-3:2017	EN ISO 11607-1:2020/A1:2023	EN ISO 11607-2:2020/A1:2023

Conformity Assessment Procedure: MDR Annex XI, Part A

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, any CS used and in relation to which conformity is declared and other relevant regulations. All supporting documentations are retained under the premises of the manufacturer.

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 München, Germany

NB Identification Number: 0123

CE Certificate No.: G26 102991 0003 Rev. 00

Expire date of the Certificate: 2030-10-13

Start of CE Marking: 2025-10-14

Signature: Tianhua 2025-10-14 Taizhou, China  
 Mr. Hua Tian, GM Date of Issue Place of Issue

