

EC Declaration of Conformity

Manufacturer: Name: Taizhou Runmei Sanitary Products Co., Ltd.
Address: South Factory of F2, Building 4, No80 Xiaqi
Road, Suchen Town, Hailing District, Taizhou, Jiangsu Province, China
SRN: CN-MF-000040341

European Representative:

Name: MedPath GmbH
Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN: DE-AR-000000087

Designation: Povidone Iodine 10% Solution

Basic UDI: 697624465PVI010RY

UDI-DI: Swab stick, 100mm-6ml
REF: PVP-3-10-SWST
UDI-DI: 0697624465010

Swab stick, 100mm-2ml
REF: PVP-1-15-SWST
UDI-DI: 0697624465027

Pad, 60x120mm-1.2ml (60x60mm, 2ply)
REF: PVP-60-60-2-P
UDI-DI: 0697624465034

Classification: Class I

Assessment Route: Annex VIII. Non invasive device / 4.1. Rule1.

We herewith declare under our sole responsibility that the abovementioned products are medical devices that meet the provisions of the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017.

DIRECTIVES

General applicable directives

Medical Device Directive: Medical Devices Regulation (EU) 2017/745 – MDR

Signature: *Tianhua*
Name:
Position: General Manager
Date: 08/10/2019

