

EC Declaration of Conformity

Item number: P265.41

Item description: RCS recycled nubuck PU pouch first aid set



Importer: XD Connects B.V.
Lange Kleiweg 6-28, 2288 GK Rijswijk, The Netherlands

Manufacturer: Danyang Sunmed Healthcare Corp.
No. 3 BeiErHuan, Danyang City, Jiangsu

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Basic UDI-DI: 697456746000035Y

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

Device Risk Class: The medical device has been assigned to class I, rule I according to Annex VIII, Medical Device Regulation (EU) 2017/745

GMDN code: 61326

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

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

Medical Device Regulation (EU) 2017/745

The manufacturer has been assessed and certified according to EN ISO 13485:2016 by the Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany

XD Connects B.V.

Name: Kevin Zhou

Function: QA

Date: May 21th, 2024


xd connects
Lange Kleiweg 6-28
2288 GK Rijswijk
the Netherlands