

Manufacturer: Sterisets International B.V.
Ketelmeer 3 – 5347 JX Oss, The Netherlands
Tel: +31 412 667 755 Email info@sterisets.com
www.sterisets.com

Medical devices:

Designation:

Bandages

Intended purpose:

To support and relief dressings and to secure other bandages

Risk Class:

According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Class I

Rule:

1

Conformity assessment route: Annex IX

ISO 9001 certificate no. : 2156451

Certification company: DEKRA Certification B.V.

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of Sterisets International B.V. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

Signature:

Name:

Jos van der Kwartel

Function:

Management representative

Place and Date:

To DoC number: DoC2156451-9 The medical devices which fall under the DoC are:

Product category: **Bandages**

REF	Designation	Basic UDI-DI	Trade name
56710	Crepe bandage 4 m x 10 cm	872059888BANDAGESF4AK	medisp
56715	Crepe bandage 4 m x 15 cm	872059888BANDAGESF4AK	medisp
56808	Orthopaedic padding 2,7 m x 7,5 cm	872059888BANDAGESF4AK	medisp
56810	Orthopaedic padding 2,7 m x 10 cm	872059888BANDAGESF4AK	medisp
56815	Orthopaedic padding 2,7 m x 15 cm	872059888BANDAGESF4AK	medisp
95200	Stockinette kreton 22 x 75 cm	872059888BANDAGESF4AK	medisp
95205	Legging 75 x 120 cm	872059888BANDAGESF4AK	medisp
95206	Leg bag 100 x 40 cm	872059888BANDAGESF4AK	medisp
95659	Leggings 79x140cm, 35g AS & AR SMS	872059888BANDAGESF4AK	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: