

Manufacturer:	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss The Netherlands Phone: +31 (0) 412 667 755 Email: info@sterisets.com www.sterisets.com
SRN:	NL-MF-000030883
Product category:	Patient warming system
Product families:	
<u>Designation:</u> Warming blankets Baby blankets	<u>Intended purpose:</u> Keep the patient warm and to prevent hypothermia by lowering body temperature Used to wrap new-born babies immediately after birth and before bath
Risk classification:	Class I
Rule:	1
Conformity assessment route:	Annex II and III
Common specifications:	Not applicable
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: Joana Pereira
Function: Management representative
Place and Date: Oss 16-02-2024

To DoC number: DoC2156451TDC5

The medical devices which fall under the DoC are:

Product category: Patient warming system

Product family: Warming blankets

Basic UDI-DI: 872059888PATWARMIF203H

REF	Designation
85100	Blanket Full body 195 x 100 cm
85110	Blanket Multi Access 195 x 100 cm
85120	Blanket Abdominal Access 192 x 180 cm
85150	Blanket Adult tube 217 x 91 cm
85200	Blanket Lower body 122 x 100 cm
85300	Blanket Upper Body ARM IN 120 x 100 cm
85310	Blanket Upper Body ARM OUT 192 x 57 cm
85400	Blanket Pediatric – Neonatal 92 x 89 cm
85410	Blanket Pediatric – Child 99 x 136 cm
85450	Blanket Pediatric Tube 117 x 56 cm
85600	Multi Purpose Hose Sock 100 x 12 cm

Product category: Patient warming system

Product family: Baby blankets

Basic UDI-DI: 872059888BABYBLANF3EZ

REF	Designation
1640	Drape baby spunlaced 50 gr/m2 75 x 120 cm white

Signature:

Name: Joana Pereira
Function: Management representative
Place and Date: Oss 16-02-2024