

Manufacturer:	Sterisets International B.V. Menhirweg 16 5342 LS The Netherlands P +31 (0)412 667 755 E 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 09-01-2025

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	Former REF
4000002	Blanket Full body 195 x 100 cm	85100
4000014	Blanket Multi Access 195 x 100 cm	85110
4000012	Blanket Abdominal Access 192 x 180 cm	85120
4000022	Blanket Surgical Access 200 x 100 cm	85130
4000010	Blanket Adult tube 217 x 91 cm	85150
4000008	Blanket Lower body 122 x 100 cm	85200
4000006	Blanket Upper Body ARM IN 120 x 100 cm	85300
4000004	Blanket Upper Body ARM OUT 192 x 57 cm	85310
4000016	Blanket Pediatric – Neonatal 92 x 89 cm	85400
4000018	Blanket Pediatric-Child 99 x 136 cm	85410
4000020	Blanket Pediatric Tube 117 x 56 cm	85450
85600	Multi Purpose Hose Sock 100 x 12 cm	85600
4100004	Blanket Over Body Medium 118 x 76 cm	Not assigned

Product category: Patient warming system

Product family: Baby blankets

Basic UDI-DI: 872059888BABYBLANF3EZ

REF	Designation	Former REF
8200028	Drape baby spunlaced 50 gr/m2 75 x 120 cm white	1640

Signature:

Name:

Joana Pereira

Function:

Management representative

Place and Date:

Oss 09-01-2025