

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:	To be determined
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: Jos van der Kwartel
Function: Management representative
Place and Date: Oss 07-08-2023

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	Full body blanket 100 x 195 cm
85110	Multi access blanket 100 x 195 cm
85120	Abdominal access blanket 192 x 180 cm
85150	Adult tube blanket 217 x 91 cm
85200	Lower torso blanket 122 x 100 cm
85300	Upper body arms in blanket 116 x 97 cm
85310	Upper body arms out blanket 57 x 192 cm
85400	Pediatric neonatal blanket 89 x 92 cm
85410	Pediatric child blanket 136 x 99 cm
85450	Pediatric tube blanket 117 x 56 cm
85600	Hose sock blanket 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: Jos van der Kwartel
Function: Management representative
Place and Date: Oss 07-08-2023