

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:

Warming blankets
Baby blanket

Intended purpose:

Prevention of hypothermia by lowering body temperature in patients during surgical intervention processes

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: DoC2156451-5 The medical devices which fall under the DoC are:

Product category: **Warming blankets, Baby blanket**

REF	Designation	Basic UDI-DI	Trade name
1640	Drape baby spunlaced 50 gr/m2 75 x 120 cm white	872059888BABYBLANF3EZ	Sterisets
85100	Full body blanket 100 x 195 cm	872059888PATWARMIF203H	Sterisets
85110	Multi access blanket 100 x 195 cm	872059888PATWARMIF203H	Sterisets
85120	Abdominal access blanket 192 x 180 cm	872059888PATWARMIF203H	Sterisets
85150	Adult tube blanket 217 x 91 cm	872059888PATWARMIF203H	Sterisets
85200	Lower torso blanket 100 x 122 cm	872059888PATWARMIF203H	Sterisets
85300	Upper body arms in blanket 94 x 124 cm	872059888PATWARMIF203H	Sterisets
85310	Upper body arms out blanket 57 x 192 cm	872059888PATWARMIF203H	Sterisets
85400	Pediatric neonatal blanket 89 x 92 cm	872059888PATWARMIF203H	Sterisets
85410	Pediatric child blanket 136 x 99 cm	872059888PATWARMIF203H	Sterisets
85450	Pediatric tube blanket 117 x 56 cm	872059888PATWARMIF203H	Sterisets
85600	Hose sock blanket 100 x 12 cm	872059888PATWARMIF203H	Sterisets

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: