


# EU Declaration of Conformity

Manufacturers Name	The Surgical Company International B.V. doing business as TSC Patient Temperature Management (PTM)
Manufacturers Address	Beeldschermweg 6F, 3821 AH Amersfoort, The Netherlands.
Single Registration Number Manufacturer	NL-MF-000001973
Authorized Representative Name (if applicable)	Not applicable
Authorized Representative Address (if applicable)	Not applicable
Product group	Mistral-Air®
Name of the Device (s)	Mistral-Air® blankets, non-sterile
Eudamed/European medical device nomenclature code	T030301
Basic UDI-DI	8719867EMDNT030301KX
Risk Classification / Rule	I / Annex VIII rule 1
Notified Body name	NA
Notified Body Address	NA
Notified Body Identification number	NA
Notified Body CE certificate number	NA
Conformity assessment route	The Surgical Company International B.V. uses the following procedures for the CE-labeling of their products according to Regulation MDR 2017/745:  Class I: EC conformity declaration according to annex IV
This declaration of conformity is issued under the sole responsibility of The Surgical Company International B.V.. We hereby declare that the medical device(s) specified in the table below meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.	
Signature:    Inette Nieveen Global Director Regulatory Affairs The Surgical Company International B.V.	Place and date of issue:  Amersfoort, 2021-11-16

**Attachment to declaration of conformity Mistral-Air® non-sterile blankets**

REF	Device name	1 <sup>st</sup> LOT	Last LOT
MA0510	Mistral-Air® Blanket, Tube	L1600320	
MA1610	Mistral-Air® Premium Warming Suit, Small	TBD	
MA1620	Mistral-Air® Premium Warming Suit, Medium	TBD	
MA1630	Mistral-Air® Premium Warming Suit, Large	TBD	
MA1640	Mistral-Air® Premium Warming Suit, X Large	TBD	
MA1710	Mistral-Air® Warming Suit, S	TBD	
MA1720	Mistral-Air® Warming Suit, M	1977034	
MA1730	Mistral-Air® Warming Suit, L	2001942998	
MA1740	Mistral-Air® Warming Suit, XL	TBD	
MA2220	Mistral-Air® Adult Plus	1950202	
MA2230	Mistral-Air® Paediatric Plus	2025101	
MA2240	Mistral-Air® Neonatal Plus	2033201	
MA2250	Mistral-Air® Lower Body Plus	1943101	
MA2260	Mistral-Air® Upper Body Plus	1944103	
MA2265	Mistral-Air® Half Upper Body Plus	1943201	
MA2270	Mistral-Air® Torso Plus	1945201	
MA2290	Mistral-Air® Blanket, Surgical Access Plus	20200305	
MA2400	Mistral-Air® Full Underbody Plus	1948201	
MA2450	Mistral-Air® Half Underbody Plus	1949202	
MA2475	Mistral-Air® Paediatric Underbody Plus	2025202	
MA3320	Mistral-Air® Premium Adult	1951101	
MA3330	Mistral-Air® Premium Paediatric	1944102	
MA3340	Mistral-Air® Premium Neonatal	2002202	
MA3350	Mistral-Air® Premium Lower Body	1943102	
MA3360	Mistral-Air® Premium Upper Body	1942201	
MA3365	Mistral-Air® Premium Half Upper Body	1944201	
MA3400	Mistral-Air® Premium Full Underbody	1949201	
MA3450	Mistral-Air® Premium Half Underbody	1949203	
MA3475	Mistral-Air® Premium Paediatric Underbody	2116202	

These disposables shall only be used with the next devices:

REF	Device name
MA1100-EU	Mistral-Air® Plus Forced Air Warming Unit (220-240V)
MA1100-US	Mistral-Air® Plus Forced Air Warming Unit (110-120V)
MA1100-JP	Mistral-Air® Plus Forced Air Warming Unit (100-110V)
MA1200-EU	Mistral-Air® Warming Unit
MA1200-US	Mistral-Air® Warming Unit
MA1200-QC-EU	Mistral-Air® Warming Unit
MA1200-QC-US	Mistral-Air® Warming Unit