DECLARATION

for Procedure Packs according to Article 22 of Regulation (EU) 2017/745 & Part II article 14 of UK MDR 2002 as amended

Medline International France SAS

5, rue Charles Lindbergh
44110 Châteaubriant France,

Hereby declare that:

(a) The mutual compatibility of the devices and other products combined in non-sterile kits has been verified and are in accordance with the manufacturers' instructions.

(b) The assembly and packing have been carried out in accordance with the manufacturer's instructions.

(c) The non-sterile kits are packed in appropriate packaging and are accompanied by relevant information to users incorporating the information to be supplied by the manufacturers of the devices and other products.

(d) Appropriate Internal monitoring, verification and validation methods are in place for assembly and packing activities related to the non-sterile kits.

Revision N° 33

GMDN Codes: 58865, 58388, 62619, 61949 and 62128

Authorised Signatory:

Stanley Dorvilly

Digitally signed by Stanley Dorvilly
DN: cn=Stanley Dorvilly, o=Medline International France, ou=Medline International France, email=Stanley.Dorvilly@medline.com, c=FR
Date: 2025.10.09 16:39:47 +02'00'

Stanley Dorvilly	44110 Châteaubriant - France	09 Oct 2025
Position: Regulatory Affairs Director	*Place*	*Date*

References *Références*	Description *Description*	GMDN
CRIE4000BKIT	KIT,VISITOR,W/GOWN,SHOE COVERS,CAP & MASK,NS	58388
CUSTQS02	Quicksuite installation pack	62619
DYKQSC02	GYNECOLOGY QUICKSUITE OR TABLE KIT	62619
KERNS001	KIT MEDICAZIONE	58865
KERNS002	KIT MEDICAZIONE CATETERE VENOSO	58865
KIT1010CE	KIT,PATIENT,GOWN,PANTS,CAP,SOCKS,CHILD,EU	61949
KIT1010KE	KIT,PATIENT,GOWN,PANTS,CAP,SOCKS,KID,EU	61949
KIT1055	KIT,GOWN,KIMONO,PANTS,UW,SOCKS,SC,PURPLE,L	61949
KIT1055XL	KIT,GOWN,KIMONO,PANTS,UW,SOCKS,SC,PURPLE,XL	61949
KIT12002XE	KIT,PATIENT,GOWN,SOCKS,CAP,BLANKET,SHEET,2XL,EU	61949
KIT14312XE	KIT,KIMONO,GOWN,PANTS,SC,CAPS, SOCKS,2XL,EU	61949
KIT1431E	KIT,KIMONO,GOWN,PANTS,SC,CAPS ,SOCKS,L,EU	61949
KIT1440	KIT,GOWN FRONT OPENING,PANTS,SOCKS,SC,CAP,L	61949
KIT1440M	KIT,GOWN FRONT OPENING,PANTS,SOCKS,SC,CAP,M	61949
KIT1440XXL	KIT,GOWN FRONT OPENING,PANTS,SOCKS,SC,CAP,2XL	61949
KIT1480E	KIT,PATIENT,GOWN,SHORT,CAP,SLIPPERS,SOCKS,L,EU	61949
KIT16212XE	KIT,KIMONO,GOWN,SOCKS,CAP,KNIT PANT,2XL,EU	61949
KIT1621E	KIT,PATIENT,KIMONO,GOWN,SOCKS,CAP,KNIT PANT,L,EU	61949
KIT2070	KIT,PATIENT,PANTS,SHIRT,SLIPPERS,CAP,L	61949
KIT2106E	KIT,PATIENT,GOWN,CAP,SLIPPERS,BAG,MASK,L,EU	61949
KIT2181E	KIT,PATIENT,SHIRT,SHORT C,CAP,SLIPPERS,BAG,XL,EU	61949
KIT2330E	KIT,PATIENT,GOWNS,SLIPPERS,BLANKET,BAG,UW,L,EU	61949
KIT24102XE	KIT,PATIENT,GOWN,PANTS,CAP,SLIPPERS,SOCKS,2XL,EU	61949
KIT2410E	KIT,PATIENT,GOWN,PANTS,CAP,SLIPPERS,SOCKS,L,EU	61949
KIT2410ME	KIT,PATIENT,GOWN,PANTS,CAP,SLIPPERS,SOCKS,M,EU	61949
KIT2441	KIT,PATIENT,GOWN,PANTS,UW,CAP,SLIPPERS,SC,2XL	61949
KIT2441XXL	KIT,PATIENT,GOWN,PANTS,UW,CAP,SLIPPERS,SC,2XL	61949
KIT3020	KIT,PATIENT,W/GOWN,SHOEC OVERS, CAP&UNDERWEAR	61949
KIT3020XXL	KIT, 2XL, PATIENT W/GOWN, SHOE COVERS, CAP&UNDERWEAR	61949
KIT3100E	KIT,PATIENT,SHIRT,CAP,SHOE COVERS,BAG,XL,EU	61949
KIT40402XE	KIT,PATIENT,GOWN,BOOT COVERS, CAP,2XL,EU	61949

References *Références*	Description *Description*	GMDN
KITV101XE	KIT,PATIENT,COVER GOWN,BOOT CO VERS,CAP,XL,EU	61949
NEBKIT001	KIT WITH FACE TENT	62128
NONE27KITK	KIT,PATIENT,CHILD,W/GOWN,SHOECOVER, CAP&UNDERWEAR	61949
NONE352XLKIT	KIT,PATIENT W/GOWN,PANTS,SHOE COVERS&CAP,2XL	61949
NONE35LKIT	KIT,PATIENT W/GOWN, PANTS,SHOE COVERS&CAP,L SIZE	61949
OC013	VAPREVENT STANDARD KIT, 2SWABS, RINSE&GEL	61949
OC513	VAPREVENT SUCTIONKIT, 1SWAB,2SWABS, RINSE, GEL	61949
OC51300	VAPREVENT SOL-FREE +2 SUCTION SWABS KIT	61949
OC572	VAPREVENT TOOTHBRUSHKIT,1SWAB, RINSE, GEL	61949
OC57200	VAPREVENT SOL-FREE +SUCTION TOOTHBRUSH KIT	61949

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