

Declaration of Conformity

Manufacturer: Ahlstrom-Munksjö Specialties Pont Audemer
15 Rue des Papetiers,
F-27500 Pont Audemer,
France

Product(s): It is a non-invasive device considered as accessories. Its intended use is Sterile Barrier System for packaging medical devices which are to be terminally sterilized.

Annex of the products is available on Annex A

Classification: These accessories have been classified according to the classification rule 1 of Annex X from **Directive 93/42/CEE**

We herewith declare that the above mentioned products meet the applicable provisions according to Annex VII of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied: **EN 868-2:2017**: Packaging materials and systems for medical devices which are to be sterilized. Part. 2: Sterilization wrap. Requirements and test methods.
ISO 11607-1:2017: Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems

Start of CE-marking: 05/2003

Date : 05/09/2018, at Pont-Audemer

Signature : Baptiste Trocquet, Quality Manager



Annex A: Non-invasive devices – Packaging material considered as accessories – Intended use: Sterile Barrier System for packaging medical devices which are to be terminally sterilized – Class I (Rule 1)

Old Product name	New Product Name	Basis Weight
CREPE PAPER		
Reliance® 310	Reliance® Crepe	60 gsm
Reliance® 310 Sensitive	Reliance® Crepe Sensitive	60 gsm
WETLAID NW		
Reliance® 335	Reliance® Dextex 100	52 gsm
Reliance® 345	Reliance® Dextex 200	57 gsm
Reliance® 360	Reliance® Dextex 300	67 gsm
SMS		
Reliance® 430	Reliance® SMS 100	35 gsm
Reliance® 440	Reliance® SMS 200	43 gsm
Reliance® 450	Reliance® SMS 300	50 gsm
Reliance® 460	Reliance® SMS 400	60 gsm
Reliance® 470	Reliance® SMS 500	70 gsm
Reliance® 485	Reliance® SMS 600	85 gsm
SOLO		
Reliance® Solo 844	Reliance® Solo 200	43+43 gsm
Reliance® Solo 855	Reliance® Solo 300	50+50 gsm
Reliance® Solo 866	Reliance® Solo 400	60+60 gsm
Reliance® Solo 877	Reliance® Solo 500	70+70 gsm
	Reliance® Solo 600	85+85 gsm
TANDEM		
	Reliance® Tandem 100	35/35 gsm
Reliance® Tandem 844	Reliance® Tandem 200	43/43 gsm
Reliance® Tandem 855	Reliance® Tandem 300	50/50 gsm
Reliance® Tandem 866	Reliance® Tandem 400	60/60 gsm
Reliance® Tandem 877	Reliance® Tandem 500	70/70 gsm
	Reliance® Tandem 600	85/85 gsm