

MAIN TECHNOLOGIES

CREPED PAPER

For external wrapping,
tray protector and overwrap



- **Bacterial barrier**
- **Liquid repellent**
- **Bulky, strong**
- **Standard and soft versions**

Manufacturing plant

We manufacture and convert our crepe paper nonwoven wrapping materials (roll goods and sheeted formats) at:

Ahlstrom-Munksjö Specialties Sa
Pont Audemer
France

Intended Use

This Sterile Barrier System is for wrapping medical devices (outer wrap) which can be terminally sterilized by the following methods: steam (121-134°C), ethylene oxide gas and low temperature formaldehyde and irradiation. We recommend that the end user validates the final packaging system as suitable with the intended sterilization process to comply with national and international regulations.

Ahlstrom-Munksjö Reliance® Creped paper range**WRAP:****Ahlstrom-Munksjö Reliance® 310**

- 60 gsm

Colors available:

**Ahlstrom-Munksjö Reliance® 310S**

- 60 gsm

Colors available:

**TRAY LINER:****Ahlstrom-Munksjö Reliance® 309**

- 80, 110 gsm

Colors available:

**TRAY PROTECTOR:****Ahlstrom-Munksjö Reliance® 309S**

- 140 gsm

Colors available:

**OVERWRAP:****Ahlstrom-Munksjö Reliance®****307 Sensitive**

- 43, 50 gsm

Colors available:





EU declaration of conformity (MDR)

CE

Registered company name : Ahlstrom-Munksjö Specialties SAS

Registered place of business : 5 Rue de la Papeterie, 59166, Bousbecque, France

Manufacturer site : 15 Rue des Papetiers, 27500, Pont-Audemer, France

Manufacturer Single Registration Number (SRN) : FR-MF-000010989

Registered trade mark : Reliance®

Intended use : Range of sterilization wraps to be used as Sterile Barrier System with main features :

- Good penetration and removal of sterilizing agent during sterilization process
- Maintain sterility of the medical devices during storage and transportation until the point of use
- Allow aseptic presentation at the point of use
- Safe to use for hospital staff and patients

Basic UDI-DI : 37008963RELIANCE2S

Product identification : Please see annex I below

Risk Class : Class I according to the classification rule 1 of Annex VIII from REGULATION (EU) 2017/745

Conformity assessment procedure : Annex IV Declaration of conformity

This EU declaration of conformity is issued under the sole responsibility of Ahlstrom-Munksjö Specialties SAS. We hereby declare that the medical devices covered by the present declaration are in conformity with REGULATION (EU) 2017/745 and with the general safety and performance requirements. This conformity is supported by our Quality Management System compliant with ISO 13485 (Certificate N° 2020/89885.1 issued by AFNOR) and by compliance with specific sterilization wraps standards EN 868-2:2017 and ISO 11607-1:2019.



Pont-Audemer, the 16th of August 2021

Baptiste Trocquet, Regulatory Affairs Manager



Annex I: List of our Reliance® Range of products covered by this EU declaration of conformity

| UDI-DI | Trade Name | SKU (A-M Code) |
|---------------|--|----------------|
| 3700896303144 | RELIANCE® CREPE BLUE - 100x100 | 0174060100100 |
| 3700896303687 | RELIANCE® CREPE BLUE - 115x115 | 0174060115115 |
| 3700896303120 | RELIANCE® CREPE BLUE - 120x120 | 0174060120120 |
| 3700896303113 | RELIANCE® CREPE BLUE - 137x137 | 0174060137137 |
| 3700896303502 | RELIANCE® CREPE BLUE - 140x140 | 0174060140140 |
| 3700896303106 | RELIANCE® CREPE BLUE - 150x150 | 0174060150150 |
| 3700896303090 | RELIANCE® CREPE BLUE - 150x180 | 0174060150180 |
| 3700896303083 | RELIANCE® CREPE BLUE - 25x25 | 0174060025025 |
| 3700896303076 | RELIANCE® CREPE BLUE - 30x30 | 0174060030030 |
| 3700896303069 | RELIANCE® CREPE BLUE - 40x40 | 0174060040040 |
| 3700896303052 | RELIANCE® CREPE BLUE - 50x50 | 0174060050050 |
| 3700896303045 | RELIANCE® CREPE BLUE - 60x60 | 0174060060060 |
| 3700896303038 | RELIANCE® CREPE BLUE - 75x75 | 0174060075075 |
| 3700896303021 | RELIANCE® CREPE BLUE - 90x90 | 0174060090090 |
| 3700896303014 | RELIANCE® CREPE GREEN - 100x100 | 0173060100100 |
| 3700896303007 | RELIANCE® CREPE GREEN - 100x140 | 0173060100140 |
| 3700896302994 | RELIANCE® CREPE GREEN - 120x120 | 0173060120120 |
| 3700896302987 | RELIANCE® CREPE GREEN - 120x140 | 0173060120140 |
| 3700896303519 | RELIANCE® CREPE GREEN - 120x160 | 0173060120160 |
| 3700896302970 | RELIANCE® CREPE GREEN - 137x137 | 0173060137137 |
| 3700896302963 | RELIANCE® CREPE GREEN - 140x140 | 0173060140140 |
| 3700896302956 | RELIANCE® CREPE GREEN - 140x160 | 0173060140160 |
| 3700896302949 | RELIANCE® CREPE GREEN - 140x180 | 0173060140180 |
| 3700896302932 | RELIANCE® CREPE GREEN - 150x130 | 0173060150130 |
| 3700896302925 | RELIANCE® CREPE GREEN - 25x25 | 0173060025025 |
| 3700896302918 | RELIANCE® CREPE GREEN - 30x30 | 0173060030030 |
| 3700896302901 | RELIANCE® CREPE GREEN - 40x40 | 0173060040040 |
| 3700896302895 | RELIANCE® CREPE GREEN - 50x50 | 0173060050050 |
| 3700896302888 | RELIANCE® CREPE GREEN - 60x60 | 0173060060060 |
| 3700896302871 | RELIANCE® CREPE GREEN - 75x75 | 0173060075075 |
| 3700896302864 | RELIANCE® CREPE GREEN - 80x40 | 0173060080040 |
| 3700896302857 | RELIANCE® CREPE GREEN - 80x80 | 0173060080080 |
| 3700896302840 | RELIANCE® CREPE GREEN - 90x90 | 0173060090090 |
| 3700896302833 | RELIANCE® CREPE SENSITIVE BLUE - 100x100 | 2722060100100 |
| 3700896302826 | RELIANCE® CREPE SENSITIVE BLUE - 120x120 | 2722060120120 |
| 3700896302819 | RELIANCE® CREPE SENSITIVE BLUE - 150x180 | 2722060150180 |

ES atitikties deklaracija (MDR)

Registruotas įmonės pavadinimas: Ahlstrom-Munksjö Specialties SAS
Registruota verslo vieta: 5 Rue de la Papeterie, 59166, Bousbecque, Prancūzija
Gamintojo svetainė: 15 Rue des Papetiers, 27500, Pont-Audemer, Prancūzija
Vienintelis(not necessary) Gamintojo registracijos numeris (SRN): FR-MF-000010989
Registruotas prekės ženklas: Reliance®
Numatytas naudojimas: Sterilizavimo, pakavimo popieriaus asortimentas, skirtas naudoti kaip sterili barjerinė sistema, kurios pagrindinės savybės:
- Geras sterilizavimo agento įsiskverbimas ir pašalinimas sterilizavimo proceso metu
- Užtikrina medicinos prietaisų sterilumą transportuojant ir saugojant
- Užtikrina medicinos prietaisų sterilumą iki naudojimo vietos
- Saugu Ligoninės personalui ir pacientui naudoti
Pagrindinis UDI-DI: 37008963RELIANCE2S
Produkto identifikavimas: žr. toliau pateiktą I priedą
Rizikos klasė : I klasė pagal 2017/745 reglamentą (ES) VIII priedą
Atitikties vertinimo procedūra : Atitikties deklaracijos IV priedas

Už šios ES atitikties deklaracijos išdavimą yra atsakinga tik „Ahlstrom-Munksjö Specialties“.
SAS. Pareiškiame, kad medicinos prietaisai, kuriems taikoma ši deklaracija, atitinka 2017/745
reglamento (ES) reikalavimus ir bendruosius saugos bei eksploatacijos savybių reikalavimus.
Atitiktį patvirtina mūsų kokybės valdymo sistema, atitinkanti ISO 13485 (sertifikato Nr.
2020/89885.1, išduota AFNOR) ir EN 868-2:2017 ir ISO 11607-1:2019 standartus.

Pont-Audemer, 2021 m. rugpjūčio 16 d
Baptiste Trocquet, reguliavimo reikalų vadovas

Daugiau informacijos rasite <https://www.ahlstrom-munksjo.com/products/medical-life-sciences-and-laboratory/sterilization-wraps/>

I priedas: mūsų „Reliance®“ asortimento produktų, kuriems taikoma ši ES atitikties deklaracija, sąrašas

