



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

40.3 p.d.

40.2 p.d.

40.1 p.d.



UDI-DI	Trade Name	SKU (A-M Code)
3700896302413	RELIANCE® CREPE WHITE - 150x130	0172060150130
3700896302406	RELIANCE® CREPE WHITE - 25x25	0172060025025
3700896303564	RELIANCE® CREPE WHITE - 25x50	0172060025050
3700896302390	RELIANCE® CREPE WHITE - 28x38	0172060028038
3700896302383	RELIANCE® CREPE WHITE - 30x30	0172060030030
3700896303588	RELIANCE® CREPE WHITE - 30x40	0172060030040
3700896302376	RELIANCE® CREPE WHITE - 40x40	0172060040040
3700896302369	RELIANCE® CREPE WHITE - 50x50	0172060050050
3700896302352	RELIANCE® CREPE WHITE - 53x23	0172060053023
3700896302345	RELIANCE® CREPE WHITE - 55x65	0172060055065
3700896302338	RELIANCE® CREPE WHITE - 60x60	0172060060060
3700896302321	RELIANCE® CREPE WHITE - 75x75	0172060075075
3700896302314	RELIANCE® CREPE WHITE - 80x80	0172060080080
3700896302307	RELIANCE® CREPE WHITE - 90x90	0172060090090
3700896301362	RELIANCE® DEXTEX 100 BLUE - 100x100	4569052100100
3700896301355	RELIANCE® DEXTEX 100 BLUE - 100x120	4569052100120
3700896301348	RELIANCE® DEXTEX 100 BLUE - 100x140	4569052100140
3700896301331	RELIANCE® DEXTEX 100 BLUE - 120x120	4569052120120
3700896301324	RELIANCE® DEXTEX 100 BLUE - 120x140	4569052120140
3700896301317	RELIANCE® DEXTEX 100 BLUE - 140x140	4569052140140
3700896301300	RELIANCE® DEXTEX 100 BLUE - 150x130	4569052150130
3700896301294	RELIANCE® DEXTEX 100 BLUE - 150x180	4569052150180
3700896301287	RELIANCE® DEXTEX 100 BLUE - 150x190	4569052150190
3700896301270	RELIANCE® DEXTEX 100 BLUE - 30x30	4569052030030
3700896301263	RELIANCE® DEXTEX 100 BLUE - 30x60	4569052030060
3700896301256	RELIANCE® DEXTEX 100 BLUE - 40x40	4569052040040
3700896301249	RELIANCE® DEXTEX 100 BLUE - 45x45	4569052045045
3700896301232	RELIANCE® DEXTEX 100 BLUE - 50x50	4569052050050
3700896301225	RELIANCE® DEXTEX 100 BLUE - 60x60	4569052060060
3700896301218	RELIANCE® DEXTEX 100 BLUE - 75x75	4569052075075
3700896301201	RELIANCE® DEXTEX 100 BLUE - 90x90	4569052090090
3700896301195	RELIANCE® DEXTEX 100 GREEN - 100x100	80090052100100
3700896301188	RELIANCE® DEXTEX 100 GREEN - 120x120	80090052120120
3700896301171	RELIANCE® DEXTEX 100 GREEN - 130x130	80090052130130
3700896301164	RELIANCE® DEXTEX 100 GREEN - 130x150	80090052130150
3700896301157	RELIANCE® DEXTEX 100 GREEN - 137x137	80090052137137
3700896301140	RELIANCE® DEXTEX 100 GREEN - 140x140	80090052140140
3700896301133	RELIANCE® DEXTEX 100 GREEN - 50x50	80090052050050
3700896301126	RELIANCE® DEXTEX 100 GREEN - 60x60	80090052060060

For more information <https://www.ahlstrom-munksjo.com/products/medical-life-sciences-and-laboratory/sterilization-wraps/>



UDI-DI	Trade Name	SKU (A-M Code)
3700896302277	RELIANCE® TANDEM CREPE SENSITIVE WHITE/GREEN - 75x75	3500060075075
3700896300501	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 100 WHITE/GREEN - 100x100	80190060100100
3700896300495	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 100 WHITE/GREEN - 120x120	80190060120120
3700896300488	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 100 WHITE/GREEN - 75x75	80190060075075
3700896300471	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 100 WHITE/GREEN - 90x90	80190060090090
3700896300464	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 GREEN/BLUE - 100x100	81010059100100
3700896300457	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 GREEN/BLUE - 120x120	81010059120120
3700896300440	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 GREEN/BLUE - 150x130	81010059150130
3700896300433	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 GREEN/BLUE - 150x180	81010059150180
3700896300426	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 GREEN/BLUE - 75x75	81010059075075
3700896300419	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 200 WHITE/BLUE - 75x75	80530059075075
3700896300402	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 300 LILAC/GREEN - 100x100	81030064100100
3700896300396	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 300 LILAC/GREEN - 120x120	81030064120120
3700896300389	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 300 LILAC/GREEN - 60x60	81030064060060
3700896300372	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 300 LILAC/GREEN - 75x75	81030064075075
3700896300365	RELIANCE® TANDEM CREPE SENSITIVE/DEXTEX 300 LILAC/GREEN - 90x90	81030064090090
3700896302260	RELIANCE® TANDEM CREPE WHITE/BLUE - 100x100	3192060100100
3700896302253	RELIANCE® TANDEM CREPE WHITE/BLUE - 60x60	3192060060060
3700896302246	RELIANCE® TANDEM CREPE WHITE/BLUE - 75x75	3192060075075
3700896302239	RELIANCE® TANDEM CREPE WHITE/BLUE - 90x90	3192060090090
3700896300358	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 100x100	80100052100100
3700896300341	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 120x120	80100052120120
3700896300334	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 120x140	80100052120140
3700896300327	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 137x137	80100052137137
3700896300310	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 50x50	80100052050050
3700896300303	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 60x60	80100052060060
3700896300297	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 75x75	80100052075075
3700896300280	RELIANCE® TANDEM DEXTEX 100 BLUE/GREEN - 90x90	80100052090090
3700896300273	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 100x100	80340055100100
3700896300266	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 120x120	80340055120120
3700896300259	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 130x150	80340055130150
3700896300242	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 60x60	80340055060060
3700896300235	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 75x75	80340055075075
3700896300228	RELIANCE® TANDEM DEXTEX 100/200 BLUE/GREEN - 90x90	80340055090090
3700896301690	RELIANCE® TANDEM DEXTEX 100/SMS 200 GREEN/BLUE - 100x100	5515048100100
3700896301683	RELIANCE® TANDEM DEXTEX 100/SMS 200 GREEN/BLUE - 120x120	5515048120120
3700896301676	RELIANCE® TANDEM DEXTEX 100/SMS 200 GREEN/BLUE - 140x140	5515048140140
3700896301669	RELIANCE® TANDEM DEXTEX 100/SMS 200 GREEN/BLUE - 75x75	5515048075075
3700896301652	RELIANCE® TANDEM DEXTEX 100/SMS 300 GREEN/BLUE - 100x100	5603051100100

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. Pareiškiamo, 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







