

This Annex I List of affected products is considered as a supplementary attachment to the FSN of FSCA-2021-07-19

Below are listed all lots of products which are affected by the FSCA-2021-07-19 and have been shipped.

Country	REF	Product description	Article No.	Lot
Canada	BO-HQV 104100	EVLP Circuit	701066978	92281068
Canada	BO-HQV 104100	EVLP Circuit	701066978	92281070
Canada	BO-HQV 104100	EVLP Circuit	701066978	92281289
Canada	BO-HQV 104100	EVLP Circuit	701066978	92281463
Canada	BO-HQV 104100	EVLP Circuit	701066978	92281832
Canada	BO-HQV 104100	EVLP Circuit	701066978	92287332
Canada	BO-HQV 104100	EVLP Circuit	701066978	92300979
Germany	H 12217	Standard Pediatric Set w. Filter	701063544	92301189
Ireland	BE-MECC 50310	National UK NRP Pack	701071853	3000151115
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92268778
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92268779
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92275073
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92275074
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92277305
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92279054
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92279847
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92281453
Netherlands	BE-HQV 34708-1	Adult Closed System with	701064517	92283742
Netherlands	BE-HQV 34708-2	Adult Closed System with	701069147	92290990
Netherlands	BE-HQV 34708-2	Adult Closed System with	701069147	92294955
Netherlands	BE-HQV 34708-2	Adult Closed System with	701069147	92298427
Netherlands	BE-HQV 51608	Adult Perfusion Set	701073988	92290629
Netherlands	BE-HQV 51608	Adult Perfusion Set	701073988	92296225
Poland	H 99100	Tubing Set for HMO 30000	701063568	92289942
Poland	H 99100	Tubing Set for HMO 30000	701063568	92290082
Poland	H 99100	Tubing Set for HMO 30000	701063568	92290083
Poland	H 99100	Tubing Set for HMO 30000	701063568	92290084
Poland	H 99100	Tubing Set for HMO 30000	701063568	92290085
Poland	H 99100	Tubing Set for HMO 30000	701063568	92292393
Saudi Arabia	BO-H 81202	Neonate Perfusion Pack	701050629	92275697
Saudi Arabia	BO-H 81202	Neonate Perfusion Pack	701050629	92285590
Saudi Arabia	BO-H 81202	Neonate Perfusion Pack	701050629	92287155
Saudi Arabia	BO-H 81202	Neonate Perfusion Pack	701050629	92291036
Saudi Arabia	BO-H 81203	Pediatric Perfusion Pack	701051078	92285591
Saudi Arabia	BO-H 81203	Pediatric Perfusion Pack	701051078	92287083
Saudi Arabia	BO-H 81203	Pediatric Perfusion Pack	701051078	92290844
Saudi Arabia	BO-H 81204	Infant Perfusion Pack	701051079	92275698

Country	REF	Product description	Article No.	Lot
Saudi Arabia	BO-H 81204	Infant Perfusion Pack	701051079	92287081
Saudi Arabia	BO-H 81204	Infant Perfusion Pack	701051079	92287345
South Africa	H 109401	Pediatric Tubing Pack	701070305	92299031
South Africa	H 109402	Infant Pack	701070307	92299032
Spain	H 61902	#Lineas 1/4x3/8	701056918	92289358
Spain	H 61902	#Lineas 1/4x3/8	701056918	92289421
Spain	H 61902	#Lineas 1/4x3/8	701056918	92297936
Spain	H 61902	#Lineas 1/4x3/8	701056918	92298005
Spain	H 32606	Ped./Mediano Pack	701066055	92291957
Spain	H 32606	Ped./Mediano Pack	701066055	92295657
Spain	H 32606	Ped./Mediano Pack	701066055	92296991
Spain	H 32606	Ped./Mediano Pack	701066055	92297717
Spain	H 32606	Ped./Mediano Pack	701066055	92301195
Spain	H 32606	Ped./Mediano Pack	701066055	92306721
Spain	H 32606	Ped./Mediano Pack	701066055	92307154
Spain	H 32606	Ped./Mediano Pack	701066055	92307578
Spain	H 32606	Ped./Mediano Pack	701066055	92308033
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	3000162008
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	92264085
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	92264086
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	92271368
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	92300209
Spain	BE-H 30803	Filtro Arterial Neonatos	701018952	92307735
Spain	H 61900	Lineas 1/4x1/4	701043741	92265640
Spain	H 61900	Lineas 1/4x1/4	701043741	92265641
Spain	H 61900	Lineas 1/4x1/4	701043741	92279031
Spain	H 61900	Lineas 1/4x1/4	701043741	92279468
Spain	H 61900	Lineas 1/4x1/4	701043741	92279750
Spain	H 61900	Lineas 1/4x1/4	701043741	92280257
Spain	H 61900	Lineas 1/4x1/4	701043741	92280685
Spain	H 61900	Lineas 1/4x1/4	701043741	92281729
Spain	H 61900	Lineas 1/4x1/4	701043741	92283721
Spain	H 61900	Lineas 1/4x1/4	701043741	92285601
Spain	H 61900	Lineas 1/4x1/4	701043741	92287082
Spain	H 61900	Lineas 1/4x1/4	701043741	92294656
Spain	H 61900	Lineas 1/4x1/4	701043741	92295624
Spain	H 61900	Lineas 1/4x1/4	701043741	92296363
Spain	H 61900	Lineas 1/4x1/4	701043741	92297229
Spain	H 61900	Lineas 1/4x1/4	701043741	92297230
Spain	H 61900	Lineas 1/4x1/4	701043741	92295879
Spain	H 32605	Set Pequeno	701066054	92260528
Spain	H 32605	Set Pequeno	701066054	92266418
Spain	H 32605	Set Pequeno	701066054	92266419

Country	REF	Product description	Article No.	Lot
Spain	H 32605	Set Pequeno	701066054	92279055
Spain	H 32605	Set Pequeno	701066054	92280895
Spain	H 32605	Set Pequeno	701066054	92285483
Sweden	HQV 89200	XVIVO Disposable Lung Circuit	701052184	92285984
Sweden	HQV 89200	XVIVO Disposable Lung Circuit	701052184	92297623
Sweden	BE-HQV 64704	MECC system	701074327	92294501
Sweden	BE-HQV 64704	MECC system	701074327	92300053
Sweden	BE-HQV 89202	XVIVO Disposable Lung Circu	701069387	92288232
Sweden	BE-HQV 89202	XVIVO Disposable Lung Circu	701069387	92295289
Sweden	BE-HQV 89202	XVIVO Disposable Lung Circu	701069387	92296479
Sweden	BE-HQV 89202	XVIVO Disposable Lung Circu	701069387	92303498
Sweden	BE-HQV 89202	XVIVO Disposable Lung Circu	701069387	92312335
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92288235
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92288247
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92291316
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92299073
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92299074
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92302779
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92306638
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92312806
Sweden	BEQ-HQV 89203	XVIVO Disposable Lung Cir	701071592	92313296
Sweden	BE-MECC 101403	MECC system w/o Reservoir	701075208	3000144146
Sweden	BE-MECC 101403	MECC system w/o Reservoir	701075208	92311592
United Kingdom	BE-MECC 50310u	National UK NRP Pack	701075048	92307584
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92271281
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92271282
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92271781
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92271782
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92275056
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92279471
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92279758
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92279759
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92287536
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92288353
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92292196
United Kingdom	H 37803	Clydebank Perfusion Pack	701045747	92296330
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	3000151115
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	3000151126
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92273977
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92273978
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92277313
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92279904
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92279905

Country	REF	Product description	Article No.	Lot
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92280935
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92313069
United Kingdom	BE-MECC 50310	National UK NRP Pack	701071853	92313070