

Customer Reply Form

1. Field Safety Notice (FSN) information				
FSN Reference number*	2020FSN_Syringes_14363S_25Sep2020			
FSN Date*	25-09-2020			
Product/ Device name*	prefilled syringes 0,9 % sodium chloride - saline - STERIFLUSH			
Product Code(s)	14363S			
Batch/Serial Number (s)	Year 2017	Year 2018	Year 2019	Year 2020
	1711437	1801001	1901018	2001035
	1712001	1801033	1901056	2001037
	1712075	1801097	1901136	2001060
	1712077	1801365	1901163	2001061
	1712091	1802002	1901214	2001069
	1712116	1802025	1901254	2001089
	1712122	1802061	1901319	2001118
	1712125	1802115	1901341	2001131
	1712127	1802116	1901359	2001133
	1712134	1802229	1901370	2001161
	1712137	1802331	1901386	2001188
	1712138	1802396	1901394	2001226
	1712144	1803001	1902042	2001250
	1712149	1803048	1902105	2001282
	1712150	1803249	1902131	2001284
		1804001	1902159	2001329
		1804133	1902202	2001344
		1804209	1902212	2001349
		1804233	1902336	2001365
		1804263	1902371	2001389
		1804269	1902372	2001452
		1804341	1902421	2001460
		1804398	1903064	2002006
		1804433	1903110	2002027
		1804438	1903164	2002045
		1804474	1903232	2002072
		1805036	1904240	2002135
		1805067	1904335	2002160
		1805107	1904347	2002173
		1805149	1905005	2002185
		1805212	1905049	2002206
		1805227	1905092	2002243
		1805291	1905156	2002257
		1805330	1905198	
		1805352	1905255	2002279
		1805378	1905257	2002292
		1805404	1905266	2003032
		1806001	1905320	2003285
		1806014	1905361	2004094
		1806045	1906128	2004156
		1806081	1906202	2004179
		1806115	1906231	2004239
		1806165	1906232	2004307

Page 2 of 8

Data Efetivo/ Effective
Date:

16/01/2020

Elaborado por
(Assinatura e Data)/Author
(Sign and Date):

16 jan 20

Revisto por
(Assinatura e
Data)/Reviewed by (Sign
and Date):

16/01/2020

Aprovado por
(Assinatura e
Data)/Approved by (Sign and
Date):

16/01/2020

Pág./Page.
1 / 5

IMP 206/2

		1806166	1906245	2004308
		1806230	1906246	2004311
		1806253	1906300	
		1806304	1906323	
		1806306	1906347	
		1806358	1907004	
		1806402	1907008	
		1006444	1907020	
		1806484	1907047	
		1806502	1907053	
		1807001	1907070	
		1807019	1907087	
		1807063	1907091	
		1807173	1907108	
		1807219	1907109	
		1807288	1907123	
		1807300	1907137	
		1807309	1907205	
		1807357	1907216	
		1808001	1907237	
		1808168	1907238	
		1808181	1907246	
		1808235	190253	
		1808245	1907303	
		1808312	1907309	
		1808316	1907314	
		1808321	1907315	
		1808322	1907351	
		1808323	1907352	
		1808343	1907358	
		1808363	1907359	
		1808367	1907361	
		1808381	1907369	
		1808401	1907378	
		1809005	1907379	
		1809117	1907380	
		1809161	1907381	
		1809327	1908002	
		1809370	1908006	
		1810006	1908078	
		1810025	1908079	
		1810040	1908122	
		1810111	1908144	
		1810127	1908161	
		1810153	1908177	
		1810154	1908187	
		1810204	1908202	
		1810263	1908228	
		1810293	1908234	
		1810294	1909001	
		1810295	1909004	
		1810390	1909022	
		1811001	1909052	
		1811017	1909057	
		1811036	1909117	
		1811040	1909138	

Data Efetivo/ Effective
Date:

16/01/2020

Elaborado por
(Assinatura e Data)/Author
(Sign and Date):

João Sousa
16 jan 20

Revisto por
(Assinatura e
Data)/Reviewed by (Sign
and Date):

Diana Sepulveda
16/01/2020

Aprovado por
(Assinatura e
Data)/Approved by (Sign and
Date):

[Assinatura]
16/01/2020

Pág./Page.
2 / 5

IMP 206/2

		1811056	1909164	Page 3 of 8
		1811117	1909185	
		1811177	1909187	
		1811179	1909197	
		1811221	1909204	
		1811262	1909212	
		1811321	1909221	
		1811330	1909222	
		1811362	1909258	
		1811375	1909278	
		1811404	1909310	
		1811422	1909318	
		1812023	1910056	
		1812161	1910057	
		1812174	1910129	
		1812211	1910414	
		1812230	1911108	
			1911245	
			1911256	
			1911299	
			1911300	
			1911387	
			1912027	
			1912043	
			1912088	
			1912089	
			1912090	
			1912107	
			1912126	
			1912127	
			1912162	
			1912166	
			1912194	
			1912195	
			1912237	
			1912238	

2. Customer Details

Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation

☐	I confirm receipt of the Field Safety Notice and that I read and understood its content*.	
--------------------------	---	--

Data Efetivo/ Effective
Date:

16/01/2020

Elaborado por
(Assinatura e Data)/Author
(Sign and Date):

16 jan 20

Revisto por
(Assinatura e
Data)/Reviewed by (Sign
and Date):

16/01/2020

Aprovado por
(Assinatura e
Data)/Approved by (Sign and
Date):

16/01/2020

Pág./Page.
3 / 5

IMP 206/2

☐	I performed all actions requested by the FSN*.			
☐	The information and required actions have been brought to the attention of all relevant users and executed*.			
☐	I have returned affected devices - enter number of devices returned and date complete.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned(DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices – enter number destroyed and date complete.	Qty:	Lot/Serial Number:	
		Qty	Lot/Serial Number:	
		N/A	Comments:	
☐	No affected devices are available for return/ destruction			
☐	Other Action (Define):			
☐	I do not have any affected devices.			
☐	I have a query please contact me (e.g. need for replacement of the product).			
Print Name*		Customer print name here		
Signature*		Customer sign here		
Date*				

4. Return acknowledgement to sender	
Email	ga-helpdesk@sterisets.eu zoe.scott@fannin.eu
Customer Helpline	
Postal Address	
Web Portal	
Fax	
Deadline for returning the customer reply form*	03-11-2020

Mandatory fields are marked with *

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Data Efetivo/ Effective
Date:

16/01/2020

Elaborado por
(Assinatura e Data)/Author
(Sign and Date):

16 Jan 20

Revisto por
(Assinatura e
Data)/Reviewed by (Sign
and Date):

16/01/2020

Aprovado por
(Assinatura e
Data)/Approved by (Sign and
Date):

16/01/2020

Pág./Page.
4 / 5

IMP 206/2

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.

Data Efetivo/ Effective
Date:

16/01/2020

Elaborado por
(Assinatura e Data)/Author
(Sign and Date):

João Sousa
16 Jan 20

Revisto por
(Assinatura e
Data)/Reviewed by (Sign
and Date):

Diana Sepulveda
16/01/2020

Aprovado por
(Assinatura e
Data)/Approved by (Sign and
Date):

[Signature]
16/01/2020

Pág./Page.
5 / 5

IMP 206/2