

Manufacturer:	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss The Netherlands Phone: +31 (0) 412 667 755 Email: info@sterisets.com www.sterisets.com
SRN:	NL-MF-000030883
Product category:	Syringes
Product families:	
<u>Designation:</u>	<u>Intended purpose:</u>
Syringes Syringes caps	To inject/infuse or withdraw fluids, for the administration of medications and for blood sampling
Risk classification:	Class I
Rule:	1 & 2
Conformity assessment route:	Annex II and III
Common specifications:	Not applicable
ISO 9001 certificate no.:	2156451
Certification company:	DEKRA Certification B.V.

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. This EU Declaration of Conformity is issued under sole responsibility of Sterisets International B.V. and according to Annex IV of the referred Regulation. This DoC is valid for the products mentioned on the addendum.

Signature:
Name: Joana Pereira
Function: Management representative
Place and Date: Oss 20-11-2023

To DoC number: DoC2156451TDC6

The medical devices which fall under the DoC are:

Product category: Syringes

Product family: Syringes

Basic UDI-DI: 872059888SYRINGESF26LN

REF	Designation
55003	Syringe 3P Luer Lock 3 ml, grad. 0,1 ml, bulk steam/eto
55005	Syringe 3P Luer Lock 5 ml, grad. 0,2 ml, bulk steam/eto
55006	Syringe 3P L L 5 ml, grad.0,5ml, bulk Print NaCl 0,9%
55010	Syringe 3P Luer Lock 10 ml, grad. 0,2 ml, bulk
55011	Syringe 3P L L 10 ml, grad 0,5 ml bulk Print NaCl 0,9%
55020	Syringe 3P Luer Lock 20 ml, grad. 1 ml, bulk steam/eto
55022	Syringe 3P Luer Lock 10 ml, grad. 0,2 ml -Red plunger
55101	Syringe 3P Luer centric 1 ml
55102	Syringe 3P Luer centric 2 ml, grad. 0,1 ml, bulk
55103	Syringe 3P luer centric 3 ml, grad. 0,1 ml, bulk steam/eto
55105	Syringe 3P Luer centric 5 ml, grad. 0,2 ml, bulk steam/eto
55110	Syringe 3P Luer centric 10 ml, bulk steam/eto
55111	Syringe 3P Luer 10ml grad 0,5 mL Print w/gly 10% Green Plung
55112	Syringe 3P L Centric 10 ml, grad 0,5 ml bulk Print Water
55121	Syringe 3P L Centric 20 ml, grad. 2,5 ml, bulk Print Water
55122	Syringe 3P L cent. 20 ml, grad. 2,5 ml, bulk Print NaCl 0,9%
55220	Syringe 3P Luer eccentric 20 ml, grad. 1,0 ml, bulk steam/et
55350	Syringe 3P catheter tip 50-60 ml, grad. 2,0 ml, bulk
55503	Syringe 3P Luer Lock 3 ml, non printed, bulk-J560M
55505	Syringe 3P Luer Lock 5 ml, non printed, bulk steam/eto
55506	Syringe 3P Luer Lock 5 ml, printed NaCl 0,9% , bulk - J560M
55510	Syringe 3P Luer Lock 10 ml, non printed, bulk steam/eto
55511	Syringe 3P Luer Lock 10 ml, printed NaCl 0,9% , bulk - J560M
55515	Syringe 3P Luer Lock 5 ml, printed NaCl 0,9% , bulk - J560M
55520	Syringe 3P Luer Lock 20 ml, non printed, bulk steam/eto
55521	Syringe 3P Luer Lock 20 ml, PRINTED NaCl 0,9%, bulk - J560M
55522	Syringe 3P Luer cent. 20 ml, non printed, bulk
55610	Syringe 3P Luer Lock 10 ml, non printed, bulk - J560M, BUTYL
55710	Syringe 3P Luer Lock 10 ml,PRINTED NaCl 0,9%bulk-J560M,BUTYL
55711	Syringe 3P Luer 10ml Print w/gly 10% Green Plung J560M,BUTYL
55712	Syringe 3P Luer 10ml Print Water J560M,BUTYL
55720	Syringe 3P Luer Lock 20 ml,PRINTED NaCl 0,9%bulk-J560M,BUTYL
55721	Syringe 3P Luer 20ml Print Water J560M,BUTYL
55722	Syringe 3P Luer 20ml Print NaCl 0,9% J560M,BUTYL

To DoC number: DoC2156451TDC6

The medical devices which fall under the DoC are:

Product category: Syringes

Product family: Syringes caps

Basic UDI-DI: 872059888SYRINCAPF34GY

REF	Designation
1810	Closure cap Luer Lock male/female red
1811	Closure cap Luer male white
1812	Closure cap Luer Lock male/female blue
1820	Closure cap yellow for prefilled syringes only
1821	Closure cap green for prefilled syringes only
1822	Closure cap white for prefilled syringes only
1823	Closure cap blue for prefilled syringes only
1824	Closure cap red for prefilled syringes only

Signature:

Name:

Joana Pereira

Function:

Management representative

Place and Date:

Oss 20-11-2023