

Manufacturer: Sterisets International B.V.
Ketelmeer 3 – 5347 JX Oss, The Netherlands
Tel: +31 412 667 755 Email info@sterisets.com
www.sterisets.com

Medical devices:

Designation:

Syringes
Syringes caps

Intended purpose:

To inject/infuse or withdraw fluids, for the administration of medications and for blood sampling

Risk Class:

According to Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
Class I

Rule:

1 & 2

Conformity assessment route: Annex IX

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: Jos van der Kwartel

Function: Management representative

Place and Date:

To DoC number: DoC2156451-6 The medical devices which fall under the DoC are:

Product category: **Syringes, Syringes caps**

REF	Designation	Basic UDI-DI	Trade name
1810	Closure cap Luer Lock male/female red	872059888SYRINCAPF34GY	medisp
1811	Closure cap Luer male white	872059888SYRINCAPF34GY	medisp
1812	Closure cap Luer Lock male/female blue	872059888SYRINCAPF34GY	medisp
1820	Closure cap yellow for prefilled syringes only	872059888SYRINCAPF34GY	medisp
1821	Closure cap green for prefilled syringes only	872059888SYRINCAPF34GY	medisp
1822	Closure cap white for prefilled syringes only	872059888SYRINCAPF34GY	medisp
1823	Closure cap blue for prefilled syringes only	872059888SYRINCAPF34GY	medisp
1824	Closure cap red for prefilled syringes only	872059888SYRINCAPF34GY	medisp
55003	Syringe 3P Luer Lock 3 ml, grad. 0,1 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55005	Syringe 3P Luer Lock 5 ml, grad. 0,2 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55006	Syringe 3P L L 5 ml, grad.0,5ml, bulk Print NaCl 0,9%	872059888SYRINGESF26LN	medisp
55010	Syringe 3P Luer Lock 10 ml, grad. 0,2 ml, bulk	872059888SYRINGESF26LN	medisp
55011	Syringe 3P L L 10 ml, grad 0,5 ml bulk Print NaCl 0,9%	872059888SYRINGESF26LN	medisp
55020	Syringe 3P Luer Lock 20 ml, grad. 1 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55101	Syringe 3P Luer centric 1 ml	872059888SYRINGESF26LN	medisp
55102	Syringe 3P Luer centric 2 ml, grad. 0,1 ml, bulk	872059888SYRINGESF26LN	medisp
55103	Syringe 3P luer centric 3 ml, grad. 0,1 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55105	Syringe 3P Luer centric 5 ml, grad. 0,2 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55110	Syringe 3P Luer centric 10 ml, bulk steam/eto	872059888SYRINGESF26LN	medisp
55111	Syringe 3P Luer 10ml grad 0,5 mL Print w/gly 10% Green Plung	872059888SYRINGESF26LN	medisp
55112	Syringe 3P L Centric 10 ml, grad 0,5 ml bulk Print Water	872059888SYRINGESF26LN	medisp
55121	Syringe 3P L Centric 20 ml, grad. 2,5 ml, bulk Print Water	872059888SYRINGESF26LN	medisp
55122	Syringe 3P L cent. 20 ml, grad. 2,5 ml, bulk Print NaCl 0,9%	872059888SYRINGESF26LN	medisp
55220	Syringe 3P Luer eccentric 20 ml, grad. 1,0 ml, bulk steam/et	872059888SYRINGESF26LN	medisp
55350	Syringe 3P catheter tip 50-60 ml, grad. 2,0 ml, bulk	872059888SYRINGESF26LN	medisp
55505	Syringe 3P Luer Lock 5 ml, non printed, bulk steam/eto	872059888SYRINGESF26LN	medisp
55506	Syringe 3P Luer Lock 5 ml, printed NaCl 0,9% , bulk - J560M	872059888SYRINGESF26LN	medisp
55510	Syringe 3P Luer Lock 10 ml, non printed, bulk steam/eto	872059888SYRINGESF26LN	medisp
55511	Syringe 3P Luer Lock 10 ml, printed NaCl 0,9% , bulk - J560M	872059888SYRINGESF26LN	medisp
55520	Syringe 3P Luer Lock 20 ml, non printed, bulk steam/eto	872059888SYRINGESF26LN	medisp
55521	Syringe 3P Luer Lock 20 ml, PRINTED NaCl 0,9%, bulk - J560M	872059888SYRINGESF26LN	medisp
55522	Syringe 3P Luer cent. 20 ml, non printed, bulk	872059888SYRINGESF26LN	medisp
55710	Syringe 3P Luer Lock 10 ml,PRINTED NaCl 0,9%bulk-J560M,BUTYL	872059888SYRINGESF26LN	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: