

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:	Trays & bowls
Product families:	
<u>Designation:</u>	<u>Intended purpose:</u>
Trays & bowls	To hold and protect medical instrumentation or medical devices during sterilization processes and subsequent storage and transportation
Risk classification:	Class I
Rule:	1
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: DoC2156451TDC1

The medical devices which fall under the DoC are:

Product category: Trays & bowls

Product family: Trays & bowls

Basic UDI-DI: 872059888TRAYBOWLF28E8

REF	Designation
213000	Tray PP 155 x 54 x 17 mm 2 compartment transp.
213001	Tray PP 151 x 76 x 18 mm 4 compartments transp.
213002	Tray boat shape PP 192 x 147 x 44 mm white w. grad.
213003	Tray catheter PP 220 x 133 x 65 mm 1000 ml w. cutout white
213004	Tray PP 180 x 95 x 25 mm 2 compartments transp.
213005	Tray PP 140 x 90 x 43 mm 1 compartment transp.
213006	Tray PP 210 x 140 x 45 mm 2 compartments transp. w. grad
213007	Tray PP 180 x 94 x 20 mm 3 compartments transp.
213008	Tray PS 144 x 88 x 20 mm 3 compartments white
213009	Tray PP 110 x 95 x 25 mm 1 compartment transp.
213011	Tray PP 148 x 41 x 17 mm 2 compartments bridge 6 mm transp.
213012	Tray PP for instruments 270 x 135 x 50 mm 1 compartment blue
213013	Tray PP for instruments 270 x 135 x 25 mm 1 compartment blue
213015	Tray PP 196 x 133 x 36 mm 1 compartment transp.
213016	Tray PP 193 x 130 x 36 mm 3 compartments transp
213018	Tray PP 196 x 133 x 36 mm 2 compartments transp.
213021	Tray PP 247 x 138 x 25 mm 1 compartment blue
213022	Tray PP 250 x 240 x 49 mm 3 compartments blue
213024	Tray PP 180 x 95 x 25 mm 3 compartments transp.
213027	Tray PP 205 x 115 x 30 mm 4 compartments transp.
213035	Tray PP 240 x 280 x 50 mm 1 compartment blue
213100	Tray PP 185 x 100 x 25 mm 2 compartments transp.
217004	Gallipot PP 30 ml Ø 39 mm height 42 mm transp. w. grad
217005	Gallipot PP 30 ml Ø 39 mm height 42 mm blue w. grad
217006	Gallipot PP 60 ml Ø 63 mm height 30 mm transp. w. grad
217007	Gallipot PP 60 ml Ø 63 mm height 30 mm blue w. grad
217008	Gallipot PP 60 ml square 79 x 60 x 22 mm transp w. grad
217009	Gallipot PP 60 ml square 79 x 60 x 22 mm blue w. grad
217010	Gallipot PP 90 ml Ø 84 mm height 24 mm transp. w. grad
217011	Bowl PP 250 ml Ø 101 mm height 54 mm transp. w. grad
217014	Gallipot PP 120 ml Ø 84 mm height 30 mm transp. w. grad
217015	Gallipot PP 120 ml Ø 84 mm height 30 mm blue w. grad
217016	Bowl PP 2000 ml Ø 225 mm height 90 mm transp. w. grad.
217017	Bowl PP 2000 ml Ø 225 mm height 90 mm blue w. grad.
217018	Bowl PP 250 ml Ø 101 mm height 54 mm blue w. grad
217019	Bowl PP 500 ml Ø 125 mm height 66 mm blue w. grad
217020	Bowl PP 1000 ml Ø 167 mm height 78 mm blue w. grad
217021	Bowl PP 500 ml Ø 125 mm height 66 mm transp. w. grad
217022	Bowl PP 1000 ml Ø 167 mm height 78 mm transp. w. grad
217023	Gallipot PP 150 ml Ø 84 mm height 41 mm transp. w. grad

DoC number: DoC2156451TDC1 Previous edition 12-07-2022

2/3

STERISETS INTERNATIONAL B.V.

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To DoC number: DoC2156451TDC1

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Product category: Trays & bowls

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Basic UDI-DI: 872059888TRAYBOWLF28E8

REF	Designation
217024	Gallipot PP 150 ml Ø 84 mm height 41 mm blue w. grad
217025	Bowl sponge 2500 ml 239 x 90 x 184 mm blue w. graduation
217040	Bowl PP 6000 ml Ø 348 mm height 112 mm blue w. grad.
217041	Bowl PP 4000 ml Ø 304 mm height 102 mm blue w. grad.
217042	Bowl PP 4000 ml Ø 304 mm height 102 mm transp. w. grad.
217043	Bowl PP 6000 ml Ø 348 height 112 mm transp. w. grad.
217055	Guidewire bowl 2500 ml 22 x 8 x 195 mm blue w. tabs
218000	JUG PP 1000 cc 160 x 115 x 126 mm with handle
218062	Jug 500 ml 159 x 117 x 67 mm transp.
218063	Quiver 92 x 73 x 204 mm
219005	Kidney bowl PP 800 ml 264 x 150 x 56 mm white w. grad.
219023	Kidney bowl PP 300 ml 214 x 120 x 43 mm blue w. grad.
219024	Kidney bowl PP 300 ml 214 x 120 x 43 mm transp. w. grad.
219025	Kidney bowl PP 800 ml 264 x 150 x 56 mm blue w. grad.
219026	Kidney bowl PP 800 ml 264 x 150 x 56 mm transp. w. grad.
217056TNS	Foldbar skal, 1000ml
217057TNS	Foldbar skal, 500ml
217058TNS	Foldbar skal, 2500ml

Signature:

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