

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:

Trays & bowls

Intended purpose:

To hold and protect medical instrumentation or medical devices during sterilization processes and subsequent storage and transportation

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

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: DoC2156451-1 The medical devices which fall under the DoC are:

Product category: **Trays & bowls**

REF	Designation	Basic UDI-DI	Trade name
213000	Tray PP 155 x 54 x 17 mm 2 compartment transp.	872059888TRAYBOWLF28E8	medisp
213001	Tray PP 151 x 76 x 18 mm 4 compartments transp.	872059888TRAYBOWLF28E8	medisp
213002	Tray boat shape PP 192 x 147 x 44 mm white w. grad.	872059888TRAYBOWLF28E8	medisp
213003	Tray catheter PP 220 x 133 x 65 mm 1000 ml w. cutout white	872059888TRAYBOWLF28E8	medisp
213004	Tray PP 180 x 95 x 25 mm 2 compartments transp.	872059888TRAYBOWLF28E8	medisp
213005	Tray PP 140 x 90 x 43 mm 1 compartment transp.	872059888TRAYBOWLF28E8	medisp
213006	Tray PP 210 x 140 x 45 mm 2 compartments transp. w. grad	872059888TRAYBOWLF28E8	medisp
213007	Tray PP 180 x 94 x 20 mm 3 compartments transp.	872059888TRAYBOWLF28E8	medisp
213008	Tray PS 144 x 88 x 20 mm 3 compartments white	872059888TRAYBOWLF28E8	medisp
213009	Tray PP 110 x 95 x 25 mm 1 compartment transp.	872059888TRAYBOWLF28E8	medisp
213011	Tray PP 148 x 41 x 17 mm 2 compartments bridge 6 mm transp.	872059888TRAYBOWLF28E8	medisp
213012	Tray PP for instruments 270 x 135 x 50 mm 1 compartment blue	872059888TRAYBOWLF28E8	medisp
213013	Tray PP for instruments 270 x 135 x 25 mm 1 compartment blue	872059888TRAYBOWLF28E8	medisp
213015	Tray PP 196 x 133 x 36 mm 1 compartment transp.	872059888TRAYBOWLF28E8	medisp
213016	Tray PP 193 x 130 x 36 mm 3 compartments transp	872059888TRAYBOWLF28E8	medisp
213018	Tray PP 196 x 133 x 36 mm 2 compartments transp.	872059888TRAYBOWLF28E8	medisp
213021	Tray PP 247 x 138 x 25 mm 1 compartment blue	872059888TRAYBOWLF28E8	medisp
213022	Tray PP 250 x 240 x 49 mm 3 compartments blue	872059888TRAYBOWLF28E8	medisp
213024	Tray PP 180 x 95 x 25 mm 3 compartments transp.	872059888TRAYBOWLF28E8	medisp
213027	Tray PP 205 x 115 x 30 mm 4 compartments transp.	872059888TRAYBOWLF28E8	medisp
213035	Tray PP 240 x 280 x 50 mm 1 compartment blue	872059888TRAYBOWLF28E8	medisp
213100	Tray PP 185 x 100 x 25 mm 2 compartments transp.	872059888TRAYBOWLF28E8	medisp
217004	Gallipot PP 30 ml Ø 39 mm height 42 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217005	Gallipot PP 30 ml Ø 39 mm height 42 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217006	Bowl PP 500 ml Ø 125 mm height 66 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217007	Gallipot PP 60 ml Ø 63 mm height 30 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217008	Gallipot PP 60 ml square 79 x 60 x 22 mm transp w. grad	872059888TRAYBOWLF28E8	medisp
217009	Gallipot PP 60 ml square 79 x 60 x 22 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217010	Gallipot PP 90 ml Ø 84 mm height 24 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217011	Bowl PP 250 ml Ø 101 mm height 54 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217014	Gallipot PP 120 ml Ø 84 mm height 30 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217015	Gallipot PP 120 ml Ø 84 mm height 30 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217016	Bowl PP 2000 ml Ø 225 mm height 90 mm transp. w. grad.	872059888TRAYBOWLF28E8	medisp
217017	Bowl PP 2000 ml Ø 225 mm height 90 mm blue w. grad.	872059888TRAYBOWLF28E8	medisp
217018	Bowl PP 250 ml Ø 101 mm height 54 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217019	Bowl PP 500 ml Ø 125 mm height 66 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217020	Bowl PP 1000 ml Ø 167 mm height 78 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217021	Bowl PP 500 ml Ø 125 mm height 66 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217022	Bowl PP 1000 ml Ø 167 mm height 78 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217023	Gallipot PP 150 ml Ø 84 mm height 41 mm transp. w. grad	872059888TRAYBOWLF28E8	medisp
217024	Gallipot PP 150 ml Ø 84 mm height 41 mm blue w. grad	872059888TRAYBOWLF28E8	medisp
217025	Bowl sponge 2500 ml 239 x 90 x 184 mm blue w. graduation	872059888TRAYBOWLF28E8	medisp
217040	Bowl PP 6000 ml Ø 348 mm height 112 mm blue w. grad.	872059888TRAYBOWLF28E8	medisp
217041	Bowl PP 4000 ml Ø 304 mm height 102 mm blue w. grad.	872059888TRAYBOWLF28E8	medisp

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REF	Designation	Basic UDI-DI	Trade name
217042	Bowl PP 4000 ml Ø 304 mm height 102 mm transp. w. grad.	872059888TRAYBOWLF28E8	medisp
217043	Bowl PP 6000 ml Ø 348 height 112 mm transp. w. grad.	872059888TRAYBOWLF28E8	medisp
217055	Guidewire bowl 2500 ml 22 x 8 x 195 mm blue w. tabs	872059888TRAYBOWLF28E8	medisp
218000	JUG PP 1000 cc 160 x 115 x 126 mm with handle	872059888TRAYBOWLF28E8	medisp
218062	Jug 500 ml 159 x 117 x 67 mm transp.	872059888TRAYBOWLF28E8	medisp
218063	Quiver 92 x 73 x 204 mm	872059888TRAYBOWLF28E8	medisp
219005	Kidney bowl PP 750 ml white	872059888TRAYBOWLF28E8	medisp
219023	Kidney bowl PP 300 ml 214 x 120 x 43 mm blue w. grad.	872059888TRAYBOWLF28E8	medisp
219024	Kidney bowl PP 300 ml 214 x 120 x 43 mm transp. w. grad.	872059888TRAYBOWLF28E8	medisp
219025	Kidney bowl PP 800 ml 264 x 150 x 56 mm blue w. grad.	872059888TRAYBOWLF28E8	medisp
219026	Kidney bowl PP 800 ml 264 x 150 x 56 mm transp. w. grad.	872059888TRAYBOWLF28E8	medisp
217056TNS	Foldbar skal, 1000ml	872059888TRAYBOWLF28E8	medisp
217057TNS	Foldbar skal, 500ml	872059888TRAYBOWLF28E8	medisp
217058TNS	Foldbar skal, 500ml	872059888TRAYBOWLF28E8	medisp

Signature:

Name: Jos van der Kwartel

Function: Management representative

Place and Date: