

<b>Manufacturer:</b>	Sterisets International B.V. Ketelmeer 3 – 5347 JX Oss The Netherlands Phone: +31 (0) 412 667 755 Email: info@sterisets.com www.sterisets.com
<b>SRN:</b>	NL-MF-000030883
<b>Product category:</b>	Wound care
<b>Product families:</b>	
<u>Designation:</u> Absorbent pads Gauze swabs & balls Maternity pads Non adherent pads Non woven swabs & balls Adhesives Cotton balls Cotton tips applicators	<u>Intended purpose:</u> To be used in cleaning wounds procedures and also as a mechanical barrier for compression or for absorption of exudates, keeping the wound dry
<b>Risk classification:</b>	Class I
<b>Rule:</b>	1, 4 & 5
<b>Conformity assessment route:</b>	Annex II and III
<b>Common specifications:</b>	Not applicable
<b>ISO 9001 certificate no.:</b>	2156451
<b>Certification company:</b>	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: DoC2156451TDC8

The medical devices which fall under the DoC are:

**Product category:** Wound care

**Product family:** Absorbent pads

**Basic UDI-DI:** 872059888ABSORPADF1RS

REF	Designation
56350	Absorbent wound dressing 10 x 10 cm Gauze Cotton Non woven
56352	Absorbent wound dressing 10 x 20 cm Gauze Cotton Non woven
56354	Absorbent wound dressing 12 x 25 cm Gauze Cotton Non woven
56356	Absorbent wound dressing 20 x 30 cm Gauze Cotton Non woven
56380	Absorbent wound dressing 10 x 10 cm
56381	Absorbent wound dressing 10 x 15 cm
56382	Absorbent wound dressing 10 x 20 cm
56383	Absorbent wound dressing 15 x 20 cm
56384	Absorbent wound dressing 15 x 25 cm
56385	Absorbent wound dressing 20 x 20 cm
56386	Absorbent wound dressing 20 x 25 cm
56387	Absorbent wound dressing 20 x 30 cm
56388	Absorbent wound dressing 20 x 40 cm
56385	Absorbent pad nw/pulp/nw 20 x 20 cm

**Product category:** Wound care

**Product family:** Gauze swabs & balls

**Basic UDI-DI:** 872059888GAUZESWAF12ZF

REF	Designation
56001	Gauze swab 5 x 5 cm 8 ply 17 th
56003	Gauze swab 5 x 5 cm 12 ply 17 th
56004	Gauze swab 5 x 5 cm 3 cm Y-slit 8 ply 17 th
56005	Gauze swab 7,5 x 7,5 cm 8 ply 17 th
56007	Gauze swab 7,5 x 7,5 cm 12 ply 17 th
56009	Gauze swab 10 x 10 cm 8 ply 17 th
56011	Gauze swab 10 x 10 cm 12 ply 17 th
56012	Gauze swab 10 x 10 cm 16 ply 17 th
56015	Gauze swab 10 x 20 cm 12 ply 17 th
56018	Gauze swab 10 x 20 cm 24 ply 17 th
56095	Gauze swab 5 x 5 cm 3 cm slit 8 ply 17 th
56201	Gauze ball 12 x 15 cm Ø 30 mm 17 th
56203	Gauze ball 20 x 17 cm Ø 35 mm 17 th
56205	Gauze ball 20 x 35 cm Ø 40 mm 17 th
56206	Gauze ball 24 x 25 cm Ø 50 mm 17 th
56208	Ball gauze 17 thr. 26 x 46 cm Ø 60 mm with elastic ring
56209	Gauze ball 33 x 55 cm Ø 75 mm 17 th

DoC number: DoC2156451TDC8 Previous edition 25-01-2023

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**Product family:** Gauze swabs & balls

**Basic UDI-DI:** 872059888GAUZESWAF12ZF

REF	Designation
56211	Gauze ball 20 x 20 cm without ring Ø 30 mm 17 th
56213	Ball gauze 17 thr. 25 x 26 cm Ø 35 mm
56217	Ball gauze 17 thr. 38 x 40 cm Ø 55 mm
56263	Swab star shaped gauze dart 17 thr. gauze size 18 x 18 cm
56267	Swab star shaped gauze dart 17 thr. gauze size 30 x 30 cm
56268	Flat gauze swab 16 x 16 mm 17 th
56269	Flat gauze swab 20 x 20 mm 17 th
56270	Flat gauze swab 30 x 30 mm 17 th
56271	Flat gauze swab 25 x 25 mm 17 th
56272	Flat gauze swab 40 x 40 mm 17 th
56273	Flat gauze swab 50 x 50 mm 17 th
56275	Flat gauze swab 60 x 60 mm 17 th
56277	Flat gauze swab 70 x 70 mm 17 th
56279	Gauze ball 39 x 43 cm without ring Fluffy type 13 th
56285	Gauze ball 30 x 30 x 30 mm Triangular 17 th
56650	Gauze ball 20 x 17 cm Wooden stick With ring Ø 35 mm 17 th
56920	Absorbent tampon Ø 65 mm With cotton thread 50 cm double 7,8 gr 20 th
56925	Absorbent tampon Ø 75 mm With cotton thread 50 cm double 8,7 gr 20 th
56930	Gauze ball 39 x 40 cm With cotton thread Ø 55 mm 17 th
56950	Tampon gynaecological gauze 10 m x 7 cm
56960	Gynaecologisch tampon 5 m x 7 cm
8821170	Skaftad rund tork gasvav nr. 14
56001PC5	Gauze swab 5 x 5 cm 8 ply 17 th
56005PC5	Gauze swab 7,5 x 7,5 cm 8 ply 17 th
56009PC5	Gauze swab 10 x 10 cm 8 ply 17 th
56013PC5	Swab gauze 8 ply 17 thr. 10 x 20 cm per 5
56201SM	Gauze ball 12 x 15 cm Ø 30 mm 17 th
56203SM	Gauze ball 20 x 17 cm Ø 35 mm 17 th
56206SM	Gauze ball 24 x 25 cm Ø 50 mm 17 th
56208SM	Gauze ball 26 x 46 cm Ø 60 mm 17 th
56271SM	Flat gauze swab 25 x 25 mm 17 th

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The medical devices which fall under the DoC are:

**Product category:** Wound care

Product family: Maternity pads

**Basic UDI-DI:** 872059888MATERPADF15R2

REF	Designation
1700	Maternity pad NW/Viscose/PE film w. strip 23 x 7,5 cm
1704	Maternity pad NW/PULP/NW PP blacksheet 10 x 35 cm
1706	Maternity pad NW/PULP/NW PP blacksheet with adhesive strip 10 x 35 cm
1709	Maternity pad NW/PULP/NW PE blacksheet w. strip 47 x 15 cm
4060	Gynaecologisch verband NW/PULP/PE film 60 x 40 cm
1706NS5	Maternity pad 10 x 35 cm with adhesive strip per 5

**Product category:** Wound care

Product family: Non adherent pads

**Basic UDI-DI:** 872059888NONADPADF18QR

REF	Designation
5211	Non-adherent dressing 7,5 x 8 cm 3 ply 275 gr Eye pad
56498	Tracheotomy swab 8 x 10 cm 3 ply 275 gr

**Product category:** Wound care

Product family: Non woven swabs & balls

**Basic UDI-DI:** 872059888NONWOSWAF19KX

REF	Designation
56286	Non woven ball 30 x 30 x 30 mm Triangular 30gr
56400	Non woven swab 5 x 5 cm 4 ply 30 gr
56401	Swab NW 6 ply 30 gr 5 x 5 cm
56402	Swab NW 4 ply 30 gr 7,5 x 7,5 cm
56403	Non woven swab 7,5 x 7,5 cm 6 ply 30 gr
56404	Non woven swab 7,5 x 7,5 cm 8 ply 30 gr
56405	Swab NW 4 ply 30 gr 10 x 10 cm
56406	Non woven swab 10 x 10 cm 6 ply 30 gr
56407	Non woven swab 10 x 20 cm 4 ply 30 gr
56409	Non woven swab 20 x 25 cm 4 ply 30 gr
56412	Non woven swab 7,5 x 7,5 cm 4 ply 40 gr

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**Product category:** Wound care

**Product family:** Non woven swabs & balls

**Basic UDI-DI:** 872059888NONWOSWAF19KX

REF	Designation
56496	Non woven swab 7,5 x 7,5 cm Y-slit 4 ply 30 gr
56497	Non woven swab 10 x 10 cm Y-slit 4 ply 30 gr
56501	Non woven ball 10 x 10 cm 30 gr Ø 20 mm
56502	Non woven ball 13 x 15 cm 30 gr Ø 35 mm
56504	Non woven ball 20 x 20 cm 30 gr Ø 40 mm
56506	Non woven ball 20 x 26 cm 30 gr Ø 50 mm
56507	Non woven ball 20 x 25 cm 30 gr Ø 55 mm
56508	Non woven ball 20 x 30 cm 30 gr Ø 60 mm
56655	Non woven ball 20 x 17 cm Wooden stick With ring Ø 35 mm 30gr
56905	Non woven ball 20 x 40 cm without ring 30 gr Roll type
56400PC5	Swab NW 4 ply 30 gr 5 x 5 cm counted per 5
56402PC5	Swab NW 4 ply 30 gr 7,5 x 7,5 cm counted per 5
56405PC5	Swab NW 4 ply 30 gr 10 x 10 cm counted per 5
56501SM	Non woven ball 10 x 10 cm 30 gr Ø 20 mm
56502SM	Non woven ball 13 x 15 cm 30 gr Ø 35 mm
56506SM	Non woven ball 20 x 26 cm 30 gr Ø 50 mm
56508SM	Non woven ball 20 x 30 cm 30 gr Ø 60 mm

**Product category:** Wound care

**Product family:** Adhesives

**Basic UDI-DI:** 872059888ADHESIVEF2J7

REF	Designation
4200	Strip adhesive 10 x 2,5 cm
4202	Strip adhesive 5 x 6 cm with cut 2,5 cm
4250	Plakstrip 11 x 1,25 cm, per 2
4252	Plakstrip 15 x 1,25 cm, per 2
4302	Plaster dressing absorbent 5 x 7 cm adhesive
4303	Plaster dressing absorbent 7 x 9 cm adhesive
4304	Plaster dressing absorbent 8 x 15 cm adhesive
95850	Strip adhesive 9 x 50 cm
95998	Velcro 2,5 x 11 cm with adhesive
95999	Velcro 2,5 x 25 cm wth adhesive

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The medical devices which fall under the DoC are:

**Product category:** Wound care

Product family: Cotton balls

**Basic UDI-DI:** 872059888COTTONBAF66F

REF	Designation
561403	Cotton ball 0,3 gram
561406	Cotton ball 0,6 gr nr. 6
561409	Cotton ball 0,9 gr nr. 9
561420	Cotton ball 2 gr nr. 20
561430	Cotton ball 3 gr nr. 30

**Product category:** Wound care

Product family: Cotton tips applicators

**Basic UDI-DI:** 872059888COTTONTIF7BP

REF	Designation
56600	Cotton tip 7,5 cm Wooden stick Small tip
56602	Cotton tip 15 cm Wooden stick Small tip
56609	Cotton tip applicator plastic small tip 15 x 0,2 cm
56610	Cotton tip 15 cm Plastic stick Large tip
56620	Cotton tip applicator 8 cm with plastic protection
56621	Cotton tip applicator 15 cm with plastic protection

**Signature:**

**Name:**

Joana Pereira

**Function:**

Management representative

**Place and Date:**

Oss 20-11-2023