

**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:**

Absorbent pads  
Gauze swabs & balls  
Maternity pads  
Non adherent pads  
Non woven swabs & balls  
Adhesives  
Cotton balls  
Cotton tips applicators

**Intended purpose:**

To be used in cleaning wounds procedures and also as a mechanical barrier for compression or for absorption of exudates, keeping the wound dry

**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, 4 & 5

**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:**

## Medical Products

To DoC number: DoC2156451-8 The medical devices which fall under the DoC are:

Product category: **Absorbent pads, Gauze swabs & balls, Maternity pads, Non adherent pads, Non woven swabs & balls, Adhesives, Cotton balls, Cotton tips applicators**

REF	Designation	Basic UDI-DI	Trade name
1700	Maternity pad NW/Viscose/PE film w. strip 23 x 7,5 cm	872059888MATERPADF15R2	medisp
1704	Maternity pad NW/PULP/NW PP blacksheet 10 x 35 cm	872059888MATERPADF15R2	medisp
1706	Maternity pad NW/PULP/NW PP blacksheet with adhesive strip 10 x	872059888MATERPADF15R2	medisp
1709	Maternity pad NW/PULP/NW PE blacksheet w. strip 47 x 15 cm	872059888MATERPADF15R2	medisp
4060	Gynaecologisch verband NW/PULP/PE film 60 x 40 cm	872059888MATERPADF15R2	medisp
4200	Strip adhesive 10 x 2,5 cm	872059888ADHESIVEF2J7	medisp
4202	Strip adhesive 5 x 6 cm with cut 2,5 cm	872059888ADHESIVEF2J7	medisp
4250	Plakstrip 11 x 1,25 cm, per 2	872059888ADHESIVEF2J7	medisp
4252	Plakstrip 15 x 1,25 cm, per 2	872059888ADHESIVEF2J7	medisp
4302	Plaster dressing absorbent 5 x 7 cm adhesive	872059888ADHESIVEF2J7	medisp
4303	Plaster dressing absorbent 7 x 9 cm adhesive	872059888ADHESIVEF2J7	medisp
4304	Plaster dressing absorbent 8 x 15 cm adhesive	872059888ADHESIVEF2J7	medisp
5211	Non-adherent dressing 7,5 x 8 cm 3 ply 275 gr Eye pad	872059888NONADPADF17QP	medisp
56001	Gauze swab 5 x 5 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56003	Gauze swab 5 x 5 cm 12 ply 17 th	872059888GAUZESWAF12ZF	medisp
56004	Gauze swab 5 x 5 cm 3 cm Y-slit 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56005	Gauze swab 7,5 x 7,5 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56007	Gauze swab 7,5 x 7,5 cm 12 ply 17 th	872059888GAUZESWAF12ZF	medisp
56009	Gauze swab 10 x 10 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56011	Gauze swab 10 x 10 cm 12 ply 17 th	872059888GAUZESWAF12ZF	medisp
56012	Gauze swab 10 x 10 cm 16 ply 17 th	872059888GAUZESWAF12ZF	medisp
56015	Gauze swab 10 x 20 cm 12 ply 17 th	872059888GAUZESWAF12ZF	medisp
56018	Gauze swab 10 x 20 cm 24 ply 17 th	872059888GAUZESWAF12ZF	medisp
56095	Gauze swab 5 x 5 cm 3 cm slit 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56201	Gauze ball 12 x 15 cm Ø 30 mm 17 th	872059888GAUZESWAF12ZF	medisp
56203	Gauze ball 20 x 17 cm Ø 35 mm 17 th	872059888GAUZESWAF12ZF	medisp
56205	Gauze ball 20 x 35 cm Ø 40 mm 17 th	872059888GAUZESWAF12ZF	medisp
56206	Gauze ball 24 x 25 cm Ø 50 mm 17 th	872059888GAUZESWAF12ZF	medisp
56208	Gauze ball 26 x 46 cm Ø 60 mm 17 th	872059888GAUZESWAF12ZF	medisp
56209	Gauze ball 33 x 55 cm Ø 75 mm 17 th	872059888GAUZESWAF12ZF	medisp
56211	Gauze ball 20 x 20 cm without ring Ø 30 mm 17 th	872059888GAUZESWAF12ZF	medisp
56213	Gauze ball 25 x 26 cm without ring Ø 35 mm 17 th	872059888GAUZESWAF12ZF	medisp
56217	Gauze ball 38 x 40 cm without ring Ø 55 mm 17 th	872059888GAUZESWAF12ZF	medisp
56263	Gauze ball 18 x 18 cm Star shaped 17 th	872059888GAUZESWAF12ZF	medisp
56267	Gauze ball 30 x 30 cm Star shaped 17 th	872059888GAUZESWAF12ZF	medisp
56268	Flat gauze swab 16 x 16 mm 17 th	872059888GAUZESWAF12ZF	medisp
56269	Flat gauze swab 20 x 20 mm 17 th	872059888GAUZESWAF12ZF	medisp
56270	Flat gauze swab 30 x 30 mm 17 th	872059888GAUZESWAF12ZF	medisp
56271	Flat gauze swab 25 x 25 mm 17 th	872059888GAUZESWAF12ZF	medisp
56272	Flat gauze swab 40 x 40 mm 17 th	872059888GAUZESWAF12ZF	medisp
56273	Flat gauze swab 50 x 50 mm 17 th	872059888GAUZESWAF12ZF	medisp
56275	Flat gauze swab 60 x 60 mm 17 th	872059888GAUZESWAF12ZF	medisp
56277	Flat gauze swab 70 x 70 mm 17 th	872059888GAUZESWAF12ZF	medisp
56279	Gauze ball 39 x 43 cm without ring Fluffy type 13 th	872059888GAUZESWAF12ZF	medisp

To DoC number: DoC2156451-8 The medical devices which fall under the DoC are:

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REF	Designation	Basic UDI-DI	Trade name
56285	Gauze ball 30 x 30 x 30 mm Triangular 17 th	872059888GAUZESWAF12ZF	medisp
56286	Non woven ball 30 x 30 x 30 mm Triangular 30gr	872059888NONWOSWAF19KX	medisp
56350	Absorbent wound dressing 10 x 10 cm Gauze Cotton Non woven	872059888ABSORPADF1RS	medisp
56352	Absorbent wound dressing 10 x 20 cm Gauze Cotton Non woven	872059888ABSORPADF1RS	medisp
56354	Absorbent wound dressing 12 x 25 cm Gauze Cotton Non woven	872059888ABSORPADF1RS	medisp
56356	Absorbent wound dressing 20 x 30 cm Gauze Cotton Non woven	872059888ABSORPADF1RS	medisp
56380	Absorbent wound dressing 10 x 10 cm	872059888ABSORPADF1RS	medisp
56381	Absorbent wound dressing 10 x 15 cm	872059888ABSORPADF1RS	medisp
56382	Absorbent wound dressing 10 x 20 cm	872059888ABSORPADF1RS	medisp
56383	Absorbent wound dressing 15 x 20 cm	872059888ABSORPADF1RS	medisp
56384	Absorbent wound dressing 15 x 25 cm	872059888ABSORPADF1RS	medisp
56385	Absorbent wound dressing 20 x 20 cm	872059888ABSORPADF1RS	medisp
56386	Absorbent wound dressing 20 x 25 cm	872059888ABSORPADF1RS	medisp
56387	Absorbent wound dressing 20 x 30 cm	872059888ABSORPADF1RS	medisp
56388	Absorbent wound dressing 20 x 40 cm	872059888ABSORPADF1RS	medisp
56400	Non woven swab 5 x 5 cm 4 ply 30 gr	872059888NONWOSWAF19KX	medisp
56401	Non woven swab 5 x 5 cm 6 ply 30 gr	872059888NONWOSWAF19KX	medisp
56402	Swab NW 4 ply 30 gr 7,5 x 7,5 cm	872059888NONWOSWAF19KX	medisp
56403	Non woven swab 7,5 x 7,5 cm 6 ply 30 gr	872059888NONWOSWAF19KX	medisp
56404	Non woven swab 7,5 x 7,5 cm 8 ply 30 gr	872059888NONWOSWAF19KX	medisp
56405	Swab NW 4 ply 30 gr 10 x 10 cm	872059888NONWOSWAF19KX	medisp
56406	Non woven swab 10 x 10 cm 6 ply 30 gr	872059888NONWOSWAF19KX	medisp
56407	Non woven swab 10 x 20 cm 4 ply 30 gr	872059888NONWOSWAF19KX	medisp
56409	Non woven swab 20 x 25 cm 4 ply 30 gr	872059888NONWOSWAF19KX	medisp
56412	Non woven swab 7,5 x 7,5 cm 4 ply 40 gr	872059888NONWOSWAF19KX	medisp
56496	Non woven swab 7,5 x 7,5 cm Y-slit 4 ply 30 gr	872059888NONWOSWAF19KX	medisp
56497	Non woven swab 10 x 10 cm Y-slit 4 ply 30 gr	872059888NONWOSWAF19KX	medisp
56498	Tracheotomy swab 8 x 10 cm 3 ply 275 gr	872059888NONADPADF17QP	medisp
56501	Non woven ball 10 x 10 cm 30 gr Ø 20 mm	872059888NONWOSWAF19KX	medisp
56502	Non woven ball 13 x 15 cm 30 gr Ø 35 mm	872059888NONWOSWAF19KX	medisp
56504	Non woven ball 20 x 20 cm 30 gr Ø 40 mm	872059888NONWOSWAF19KX	medisp
56506	Non woven ball 20 x 26 cm 30 gr Ø 50 mm	872059888NONWOSWAF19KX	medisp
56507	Non woven ball 20 x 25 cm 30 gr Ø 55 mm	872059888NONWOSWAF19KX	medisp
56508	Non woven ball 20 x 30 cm 30 gr Ø 60 mm	872059888NONWOSWAF19KX	medisp
56600	Cotton tip 7,5 cm Wooden stick Small tip	872059888COTTONTIF7BP	medisp
56602	Cotton tip 15 cm Wooden stick Small tip	872059888COTTONTIF7BP	medisp
56609	Cotton tip applicator plastic small tip 15 x 0,2 cm	872059888COTTONTIF7BP	medisp
56610	Cotton tip 15 cm Plastic stick Large tip	872059888COTTONTIF7BP	medisp
56620	Cotton tip applicator 8 cm with plastic protection	872059888COTTONTIF7BP	medisp
56621	Cotton tip applicator 15 cm with plastic protection	872059888COTTONTIF7BP	medisp
56650	Gauze ball 20 x 17 cm Wooden stick With ring Ø 35 mm 17 th	872059888GAUZESWAF12ZF	medisp
56655	Non woven ball 20 x 17 cm Wooden stick With ring Ø 35 mm 30gr	872059888NONWOSWAF19KX	medisp
56905	Non woven ball 20 x 40 cm without ring 30 gr Roll type	872059888NONWOSWAF19KX	medisp
56920	Absorbent tampon Ø 65 mm With cotton thread 50 cm double 7,8 gr	872059888GAUZESWAF12ZF	medisp
56921	Tampon absorbent XR 65 mm gauze 20 thr. with tie	872059888GAUZESWAF12ZF	medisp

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REF	Designation	Basic UDI-DI	Trade name
56925	Absorbent tampon Ø 75 mm With cotton thread 50 cm double 8,7 gr	872059888GAUZESWAF12ZF	medisp
56930	Gauze ball 39 x 40 cm With cotton thread Ø 55 mm 17 th	872059888GAUZESWAF12ZF	medisp
56950	Tampon gynaecological gauze 10 m x 7 cm	872059888GAUZESWAF12ZF	medisp
56960	Gynaecologisch tampon 5 m x 7 cm	872059888GAUZESWAF12ZF	medisp
95850	Strip adhesive 9 x 50 cm	872059888ADHESIVEF2J7	medisp
95998	Velcro 2,5 x 11 cm with adhesive	872059888ADHESIVEF2J7	medisp
95999	Velcro 2,5 x 25 cm wth adhesive	872059888ADHESIVEF2J7	medisp
561403	Cotton ball 0,3 gram	872059888COTTONBAF66F	medisp
561406	Cotton ball 0,6 gr nr. 6	872059888COTTONBAF66F	medisp
561409	Cotton ball 0,9 gr nr. 9	872059888COTTONBAF66F	medisp
561420	Cotton ball 2 gr nr. 20	872059888COTTONBAF66F	medisp
561430	Cotton ball 3 gr nr. 30	872059888COTTONBAF66F	medisp
8821170	Skaftad rund tork gasvav nr. 14	872059888GAUZESWAF12ZF	medisp
1706NS5	Maternity pad 10 x 35 cm with adhesive strip per 5	872059888MATERPADF15R2	medisp
56001PC5	Gauze swab 5 x 5 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56005PC5	Gauze swab 7,5 x 7,5 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56009PC5	Gauze swab 10 x 10 cm 8 ply 17 th	872059888GAUZESWAF12ZF	medisp
56013PC5	Swab gauze 8 ply 17 thr. 10 x 20 cm per 5	872059888GAUZESWAF12ZF	medisp
56201SM	Gauze ball 12 x 15 cm Ø 30 mm 17 th	872059888GAUZESWAF12ZF	medisp
56203SM	Gauze ball 20 x 17 cm Ø 35 mm 17 th	872059888GAUZESWAF12ZF	medisp
56206SM	Gauze ball 24 x 25 cm Ø 50 mm 17 th	872059888GAUZESWAF12ZF	medisp
56208SM	Gauze ball 26 x 46 cm Ø 60 mm 17 th	872059888GAUZESWAF12ZF	medisp
56271SM	Flat gauze swab 25 x 25 mm 17 th	872059888GAUZESWAF12ZF	medisp
56400PC5	Swab NW 4 ply 30 gr 5 x 5 cm counted per 5	872059888NONWOSWAF19KX	medisp
56402PC5	Swab NW 4 ply 30 gr 7,5 x 7,5 cm counted per 5	872059888NONWOSWAF19KX	medisp
56405PC5	Swab NW 4 ply 30 gr 10 x 10 cm counted per 5	872059888NONWOSWAF19KX	medisp
56501SM	Non woven ball 10 x 10 cm 30 gr Ø 20 mm	872059888NONWOSWAF19KX	medisp
56502SM	Non woven ball 13 x 15 cm 30 gr Ø 35 mm	872059888NONWOSWAF19KX	medisp
56506SM	Non woven ball 20 x 26 cm 30 gr Ø 50 mm	872059888NONWOSWAF19KX	medisp
56508SM	Non woven ball 20 x 30 cm 30 gr Ø 60 mm	872059888NONWOSWAF19KX	medisp

**Signature:**

**Name:** Jos van der Kwartel

**Function:** Management representative

**Place and Date:**