

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:	Examination accessories
Product families:	
<u>Designation:</u>	<u>Intended purpose:</u>
Spatulas	To enter the mouth and depress the tongue to allow the examination of the mouth and throat
Washing gloves	To wash patients or users to ensure asepsis during the procedure
Tourniquets	Used to stop the flow of blood through a vein or artery
Cleaning foam stick	Used for cleaning and disinfection the local area
Risk classification:	Class I
Rule:	1 & 5
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: DoC2156451TDC10

The medical devices which fall under the DoC are:

Product category: Examination accessories

Product family: Spatulas

Basic UDI-DI: 872059888SPATULASF22AX

REF	Designation
215014	Tongue depressor woden 140 x 14 x 1,6 mm

Product category: Examination accessories

Product family: Washing gloves

Basic UDI-DI: 872059888WASHGLOVF295H

REF	Designation
71000	Washing glove 16 x 23 cm

Product category: Examination accessories

Product family: Tourniquets

Basic UDI-DI: 872059888TOURNIQUF35RG

REF	Designation
215058	Tourniquet 49 x 3,0 cm folded including silicone band
215059	Tourniquet 49 x 2,5 cm folded including silicone band

To DoC number: DoC2156451TDC10

The medical devices which fall under the DoC are:

Product category: Examination accessories

Product family: Cleaning foam stick

Basic UDI-DI: 872059888CLEANFOAF5GT

REF	Designation
5874	Foam (white) stick (green),15 cm, ultra-sonic sealed,bulk NS
5875	Lollyprep with handle
5876	Foam stick dental green 15 cm bulk
5880	Lollyprep with handle 16 cm
58755	Desinfectiedepper foam
4389T	Foam sponge white
5875SM	Lollyprep with handle
5876NS5	Foam sticks dental green 15 cm per 5

Signature:

Name:

Joana Pereira

Function:

Management representative

Place and Date:

Oss 20-11-2023