

<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>	Saline solution in spray
<b>Product families:</b>	
<u>Designation:</u> Nasal Sprays	<u>Intended purpose:</u> The isotonic saline solutions are intended for nasal hygiene and the hypertonic saline solutions are indicated for nasal congestion relief
<b>Risk classification:</b>	Class I
<b>Rule:</b>	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 24-05-2024

To DoC number: DoC2156451TDC12

The medical devices which fall under the DoC are:

**Product category:** Saline solution in spray

**Product family:** Nasal Sprays

**Basic UDI-DI:** 872059888NASALSPRF37VG

REF	Designation
5010SE	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby Senti2
5030	Nasal Spray Seawater Isotonic (0,9%)100ml Medium Adult Steri
5010SA	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby Sanian
5010VI	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby Visclean
5010WE	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby Wells
5011NA	Nasal Spray Seawater Isotonic (0,9%) 100ml Baby-Kids Nasumer
5011UN	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby-Kids Unifar
5011VI	Nasal Spray Seawater Isotonic (0,9%) 100 ml Baby-Kids Viscle
5013GL	Nasal Spray Saline Isotonic (0,9%) 125 ml Adult Daily Hygien
5014GL	Nasal Spray Saline Isotonic (0,9%) 50 ml Adult Daily Hygiene
5015GL	Nasal Spray Saline Isotonic (0,9%) 125 ml Kids Daily Rinse
5016GL	Nasal Spray Saline Isotonic (0,9%) 50 ml Kids Daily Rinse
5017GL	Nasal Spray Saline Hypertonic (2,2%) 125 ml Adult Cold & Flu
5018GL	Nasal Spray Saline Hypertonic (2,2%) 125 ml Kids Cold & Flu
5040WE	Nasal Spray Seawater Isotonic (0,9%) 100 ml Adult Wells

**Signature:**

**Name:** Joana Pereira  
**Function:** Management representative  
**Place and Date:** Oss 24-05-2024