



INTERNATIONAL

*Surgical products designed and manufactured by the Scanlan family since 1921*

**DECLARATION OF CONFORMITY**  
medical devices

We hereby declare that the distributed CE marked products, specified in the annexed productlist, as mentioned and falling within class I, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex VII of the EC-Directive 93/42/EEC. This declaration is supported by the Quality System certification based on the harmonized standard ISO 13485:2016, Quality System Certificate, with reference number 3820026, first issued on November 16, 2018, and delivered by DEKRA Certification B.V.

This Declaration of Conformity covers Sterilization Tray Product Family as specified in the productlist belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at:

Scanlan International, Inc.,  
St. Paul, Minnesota, 55107, USA

  
Mark Watson  
Vice President, Corporate Regulatory/Quality

Authorized Representative:  
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Effective: April 16, 2021

Annex: Productlist Sterilization Tray Product Family

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## Productlist – Instrument Sterilization Trays Product Family

This productlist belongs to the Declaration of Conformity covering Class I Instrument Sterilization Trays, Technical Construction File # 6 and specifies the CE marked products concerned that Scanlan International, Inc. intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices. The following list identifies the products by name and catalog number and by date first sold to the European Community.

<u>Catalog Number</u>	<u>Product Name</u>	<u>CE Mark First Applied</u>
Instrument Sterilization Trays		
Q28105-8	SCANLAN® Metal Sterilization Tray, with complete mat on bottom 10" x 15" x 1.5" (25x38x3.8cm)	March 20, 2009
2081-11 and 2081-11S 2081-11EN	6" x 10" x .7" / 15.2 x 25.4 x 1.8 cm with silicone mat, instrument capacity 10+ <b>Sample (For Visual Evaluation Only)</b> 6" x 10" x 3/4" / 15.2x25.4x1.8 cm, Instrument capacity 10+ (For Evaluation Use Only)	May 23, 1997 June 30, 1997 November 20, 2008
2081-12 and 2081-12N and 2081-12EN and 2081-12S	10" x 15" x .7" / 15.2 x 25.4 x 1.8 cm with silicone mat, instrument capacity 20+ 10" x 15" x .7" / 15.2 x 25.4 x 1.8 <b>Sample (For Visual Evaluation Only)</b> <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 August 9, 2007 May 25, 2007 June 30, 1997
2081-21 and 2081-21S	6" x 10" x .7" / 15.2 x 25.4 x 1.8 cm with additional tray insert and extra silicone mat, instrument capacity 10+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2081-23 and 2081-23S and 2081-23N and 2081-23E	10" x 15" x 1.5" / 25.4 x 38.1 x 3.8 cm with additional 1/2 tray and insert and extra silicone mat, instrument capacity 30+ <b>Sample (For Visual Evaluation Only)</b> <b>(For Evaluation Use Only)</b>	May 23, 1997 June 30, 1997 February 1, 2005 May 23, 1997
2081-24 and 2081-24S	10" x 15" x 1.5" / 25.4 x 38.1 x 3.8 cm with additional tray and insert and extra silicone mat, instrument capacity 30+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2082-10 and 2082-10S	6" x 10" x 1.5" / 15.2 x 25.4 x 3.8 cm deep base with silicone mat, instrument capacity 10+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2082-20 and 2082-20S	10" x 15" x 1.5" / 15.2 x 25.4 x 3.8 cm deep base with silicone mat, instrument capacity 20+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2083-01 and 2083-01S	2" x 6" x .7" / 5.1 x 15.2 x 1.8 cm with silicone mat, instrument capacity 1-2 <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2083-02 and 2083-02S	3" x 6" x .7" / 7.6 x 15.2 x 1.8 cm with silicone mat, instrument capacity 3 <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2083-03 and 2083-03S	3" x 7.8" x .7" / 7.6 x 19.8 x 1.8 cm with silicone mat, instrument capacity 3 <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2083-05 and 2083-05S	5.5" x 9.6" x .7" / 14 x 24.4 x 1.8 cm with silicone mat, instrument capacity 10 <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997
2083-16 and 2083-16S	7.5" x 13" x .7" / 7.6 x 15.2 x 1.8 cm with silicone mat, instrument capacity 3 <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 June 30, 1997

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<u>Catalog Number</u>	<u>Product Name</u>	<u>CE Mark First Applied</u>
2083-19 and <b>2083-19S</b>	10" x 18" x .7" / 25.5 x 45.8 x 1.8 cm with silicone mat, instrument capacity 30+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2084-07 and <b>2084-07S</b>	4.5" x 8.5" x 1.5" / 11.4 x 21.6 x 3.8 cm with additional tray insert and extra silicone mat, instrument capacity 10+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2084-12 and <b>2084-12S</b>	8" x 9.5" x 1.5" / 20.3 x 24.1 x 3.8 cm with additional tray insert and extra silicone mat, instrument capacity 20+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2084-17 and <b>2084-17S</b>	6.3" x 11.8" x 1.5" / 16 x 30 x 3.8 cm with additional tray insert and extra silicone mat, instrument capacity 20+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2084-20 and <b>2084-20S</b>	9.7" x 17.8" x 1.5" / 24.6 x 45.2 x 3.8 cm with additional tray insert and extra silicone mat, instrument capacity 30+ <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2084-112 and <b>2084-112S</b>	9.5" x 8" x 1.5" / 23.5 x 16 x 3.8 cm with tray insert and silicone mat <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2085-30 and <b>2085-30S</b>	Endoscopic Sterilization Tray, Small, 8.25" x 18" x 1.75" / 21 x 45.7 x 4.4 cm <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2085-40 and <b>2085-40S</b>	Endoscopic Sterilization Tray, Large, 8.25" x 22" x 1.75" / 21 x 55.9 x 4.4 cm <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2085-41 and <b>2085-41S</b>	Endoscopic Sterilization Tray, Double, 8.25" x 22" x 3.5" / 21 x 55.9 x 8.9 cm <b>Sample (For Visual Evaluation Only)</b>	May 23, 1997 <b>June 30, 1997</b>
2130-01	Identification Tags for SCANLAN® Puskas™ Coronary Instruments Basic Set (includes 9 ID tags, one for each instrument in the set)	March 14, 2006
2130-02	Identification Tags for SCANLAN® Puskas™ Coronary Instruments Supplemental Set (includes 6 ID tags, one for each instrument in the set)	March 14, 2006
2130-03	Identification Tags for SCANLAN® Puskas™ IMA Dissection Set (includes 4 ID tags, one for each instrument in the set)	March 14, 2006
2133-03	Small Parts Container, 1.5"x3.5"x1", with mat and hardware	February 13, 2009
2133-03E	Small Parts Container, 1.5"x3.5"x1", with mat and hardware	February 13, 2009
2135-03	Sterilization Tray	October 31, 2016
2135-04	Metal Sterilization Tray	October 31, 2016
2138-01 and <i>2138-01N and</i> <b>2138-01S</b>	Metal Sterilization Tray, 10" x 10" x 1.5" / 25 cm x 25 cm x 3.8 cm <b>Sample (For Visual Evaluation Only)</b>	August 13, 2004 <i>February 1, 2005</i> <b>August 13, 2004</b>
2138-03	Metal Sterilization Tray, silver-grey color, 10"x10"x1.5"	July 28, 2008
2138-03E	Metal Sterilization Tray, silver-grey color, 10"x10"x1.5", Evaluation Only	October 10, 2009
<i>2138-03N</i>	<i>Metal Sterilization Tray, silver-gray color, 10"x10"x1.5" / 25x25x3.8 cm</i>	<i>October 7, 2008</i>
2139-03	Scanlan Metal Sterilization Tray, silver gray color, full silicone mat on base, With partial mat on cover, 10"x15"x1.5" (25cm x 38cm x 3.8 cm)	
2139-03E	Scanlan Metal Sterilization Tray, silver gray color, full silicone mat on base, With partial mat on cover, 10"x15"x1.5" (25cm x 38cm x 3.8 cm) *FOR EVALUATION ONLY*	March 30, 2010
2140-01 and	Metal Sterilization Tray, 10" x 10" x 1.5" / 25 cm x 25 cm x 3.8 cm	August 13, 2004

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<b>2140-01S</b>	<b>Sample (For Visual Evaluation Only)</b>	
2140-03	Metal Sterilization Tray, 10"x15"x1.5"	November 12, 2007
<b>2140-03E</b>	<b>Metal Sterilization Tray, 10"x15"x1.5", Evaluation only</b>	<b>November 27, 2007</b>
<b>2140-03EN</b>	<b>Metal Sterilization Tray, 10"x15"x1.5", Evaluation only</b>	<b>November 27, 2007</b>
2140-03N	Metal Sterilization Tray, 10"x15"x1.5",	November 27, 2007
2141-02 and 2141-02N and <b>2141-02S</b>	Metal Sterilization Tray, 10" x 10" x 2 5/8" / 25 cm x 25 cm x 6.6 cm  <b>Sample (For Visual Evaluation Only)</b>	August 13, 2004 February 1, 2005 <b>August 13, 2004</b>
2141-03	SCANLAN® Metal Sterilization Tray, 10" x 15" x 2 5/8" / 25 x 38 x 6.6 cm	February 15, 2007
2141-03N	SCANLAN® Metal Sterilization Tray, 10" x 15" x 2 5/8" / 25 x 38 x 6.6 cm	February 16, 2007
2142-03	SCANLAN® Metal Sterilization Tray, silver gray color, silicone mat extends width of base, with tray insert, 10"x15"x 2.6" / 25x38x6.6 cm.	December 9, 2008
2145-02N	SCANLAN® Metal Sterilization Tray, 16"x10"x 2 1/2"	July 28, 2008
2145-02EN	SCANLAN® DURA CLOSURE SET METAL STERILIZATION TRAY 16X10X21/2"	October 10, 2009
2145-03	SCANLAN® Metal Sterilization Tray, 10.5 X 21 X 2.5" / 27 X 53 X 6.5 cm	February 15, 2007
2146-03	SCANLAN® Metal Sterilization Tray	January 22, 2010
2150-03	SCANLAN® V.I.P.™ Metal Sterilization Tray	October 31, 2016
2151-03	SCANLAN® Metal Sterilization Tray 17x101, 2x11 2"	July 15, 2019
2160-03	SCANLAN® V.I.P.™ Metal Sterilization Tray single layer	February 20, 2020
2161-03	SCANLAN® V.I.P.™ Metal Sterilization Tray double layer	February 20, 2020
2162-03	SCANLAN® V.I.P.™ Cleaning Basket	April 16, 2021
3303-04	Replacement mat for SCANLAN® Tray #2133-03	April 23, 2009
3303-05	Screw and nut for SCANLAN® Tray #2133-03	April 23, 2009
3784-80	Micro/Neuro Sterilizing Tray/Case with Rack, 9" x 5 1/8" x 2" / 23 x 13 x 5 cm, instrument capacity 10+	May 23, 1997
4003-04	Replacement mat for SCANLAN® Tray #2140-03	April 23, 2009
4004-130	Advantage™ Sterilization Tray	May 15, 2002
4004-130 and 4004-130N	Advantage™ Sterilization Tray	May 15, 2002 February 1, 2005
8008-62	Valued Instrument Protection (V.I.P.™) System, Sterilization Tray System 9" x 12" / 22.8 x 30.5 cm tray with silicone mat and soft-sided carrying case, instrument capacity 8 –12	May 23, 1997
<b>8008-62E</b>	<b>(For Evaluation Use Only- without soft-sided carrying case)</b>	<b>May 23, 1997</b>
<b>8008-62S</b>	<b>(For Visual Evaluation Only – with soft-sided carrying case)</b>	<b>May 23, 1997</b>
8008-63	replacement mat	May 23, 1997
8008-64	replacement tray	May 23, 1997
8008-65	replacement soft-sided carrying case	May 23, 1997
8008-66	SCANLAN® Instrument Sterilization tray, 12"x 9"x .7" (30.5 cm x 23 cm x 1.8 cm) with Silicone mat, instrument capacity 8-12, metal clasp	May 23, 1997  August 6, 2008
9009-931	SUNDT™ Sterilization/Storage Case	May 23, 1997
9009-932	SUNDT™ Sterilization/Storage Case	May 23, 1997
9009-933	SUNDT™ Sterilization/Storage Case	May 23, 1997
9009-934 and	SUNDT™ Graduated Suction System Sterilization/Storage Tray, 6" x 10" x 1.5" / 15.2 x 25.4 x 3.8 cm, fits all lengths, holds 7 tips plus handles	November 21, 2001

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### **Catalog**

#### **Number**

#### **Product Name**

#### **CE Mark First Applied**

**9009-934S and (For Visual Evaluation Only)**

**November 21, 2001**

**9009-934N and**

**February 1, 2005**

**9009-934E (For Evaluation Use Only)**

**January 16, 2002**

**END OF PRODUCTLIST**