



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 the Suction Instrument 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 Suction Instrument Product Family

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## Productlist – Suction Instrument Product Family

This product belongs to the Declaration of Conformity covering Class I Suction Instruments, Technical Construction File #27 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 of 14 June 1993 concerning medical devices. The following list identifies the products by name and catalog number and by date first sold to the European Community.

Catalog Number	Product Name	CE Mark First Applied
Q29142-9	D'Amico Suction Instrument, straight, blunt tip, Yankauer handle 23 ½"/ 60cm	December 15, 2009
Q29150-9	D'Amico Suction Instrument, straight, blunt Tip, Wolf-style tip, Yankauer handle 17 ¾"/45.5cm	December 21, 2009
Q29163-9	Thoracoscopic Wolf Suction Instrument (3.2mm) w/fixed suction, curved blunt tip, Insulated 14 ¼"/36cm	January 8, 2010
10-23C	Pool Suction Tube, Curved, 23 Fr., 33 cm	May 23, 1997
10-30	Pool Suction Tube, Curved, 30 Fr., 33 cm	May 23, 1997
1001-09	Heparin Flushing Needles	May 23, 1997
4909-96	Muscle Biopsy Cannula, 5 mm	May 23, 1997
4909-97	Muscle Biopsy Cannula, 6 mm, three pieces	May 23, 1997
4004-126	Suction Cleaning Stylet	May 23, 1997
4004-126N	<i>Suction Cleaning Stylet</i>	February 1, 2005
4004-127	Irrigating Stylet for Suction Forceps	February 25, 2004
4004-127N	<i>Irrigating Stylet for Suction Forceps</i>	February 1, 2005
9009-900	Thoracoscopic D'Amico 5mm suction Instrument, straight blunt tip, 31.5 cm working length, 17-3/4" / 45 cm	October 3, 2008
9009-901	Thoracoscopic Wolf Suction Instrument (5 mm) with variable suction handle, Straight blunt tip, 31.5 cm working length, 17-3/4"/45 cm	October 3, 2008
9009-905	SCANLAN® Brush Set, pack of 10, for 5 mm D'Amico, 5 mm Dennis and 3.2 mm Wolf Thoracoscopic Suction Instruments, total length 19" / 48.3 cm	October 3, 2008
9009-908	Thoracoscopic Wolf Suction Instrument (3MM) curved blunt tip	October 3, 2008
9009-909	Thoracoscopic Wolf Suction Instrument (3.3mm), with variable suction handle, curved blunt tip, 17 cm working length	October 3, 2008
9009-910	Thoracoscopic Wolf Suction Instrument (3.2 mm), curved blunt tip, 22 cm working length, 14-1/4"/36.3 cm total length	October 3, 2008
9009-911	Thoracoscopic Wolf Suction Instrument (3.2 mm), curved blunt tip, 22 cm working length, 14-1/4"/36.3 cm total length, variable suction	October 3, 2008
9009-912	Thoracoscopic Wolf Suction Instrument	October 31, 2016
9009-913	Thoracoscopic Wolf Suction Instrument	October 31, 2016
9009-914	Dennis Suction Instrument, 22 cm WL/ 36.3 cm TL	November 1, 2010
9009-914K	Dennis Suction Instrument, knurled tip	April 16, 2021
9009-915	Dennis Suction Instrument, variable, 22 cm WL/ 36.3 cm TL	November 1, 2010
9009-916	Dennis Suction Instrument, Fixed, 32 cm WL/ 45.5.cm TL	November 1, 2010
9009-916K	Dennis Suction Instrument, knurled tip	April 16, 2021
9009-917	Dennis Suction Instrument, Variable, 32 cm WL/ 45.5 cm TL	November 1, 2010
9009-918	Brush Set, pack of 10 for Tube of Thoracoscopic Wolf Suction Instrument	November 1, 2010
9009-919	Brush Set, pack of 10 for handle of Thoracoscopic Wolf Suction Instrument	November 1, 2010
9009-920	D'Amico 10 mm Suction Instrument, straight blunt tip	May 11, 2009
9009-921	D'Amico 10 mm Variable Suction Instrument	May 11, 2009
9009-922	D'Amico Suction Brush Set; Pack of 10	May 11, 2009
9009-924	D'Amico 10 mm Suction Instrument	October 31, 2016
9009-925	D'Amico 10 mm Variable Suction Instrument	October 31, 2016
SUNDT™ Graduated Suction System		
9009-928	Brush Set, pack of 10	February 1, 2005

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Catalog Number	Product Name	CE Mark First Applied
9009-928S	Sample	February 1, 2005
9009-928N	Brush Set, pack of 10	May 23, 1997
9009-928-3	Stylet for Sundt Suction Tip 3 FR, pack of 10 (Short for 940, 950, 960, 970 sets)	August 21, 2008
9009-928-3N	Stylet for Sundt Suction Tip 3 FR (Short for 940, 950, 960, 970 sets)	August 11, 2008
9009-929	Brush Set, pack of 10	May 23, 1997
9009-929N	Brush Set, pack of 10	May 23, 1997
9009-929-3	Stylet for Sundt Suction Tip 3FR, pack of 10 (Long for 980, 990 sets)	August 20, 2008
9009-929-3N	Stylet for Sundt Suction Tip 3FR, pack of 10 (Long for 980, 990 sets)	August 25, 2008
9009-930	Universal Suction Handle (7.5 cm)	May 23, 1997
9009-930N	<i>Universal Suction Handle (7.5 cm)</i>	February 1, 2005
9009-940 and 9009-940N	SUNDT™ Graduated Suction System with 4 1/2" / 11.5 cm Rotatable Tips, Universal Suction Handle 3" / 7.5 cm, 7 Suction Tips - diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr., 9 fr., 11 fr., and <i>sterilization/storage case</i>	May 23, 1997  February 1, 2005
9009-941P	Special Suction Tip (Pynchon Tip), 3 French, 4 1/2" / 11.5 cm	May 23, 1997
Variable Suction Rotatable Tips, 4 1/2" / 11.5 cm (for Systems #9009-940 and #9009-940N))		
9009-941	3 French	May 23, 1997
9009-941N	<i>3 French</i>	February 1, 2005
9009-942	4 French	May 23, 1997
9009-942N	<i>4 French</i>	February 1, 2005
9009-943	5 French	May 23, 1997
9009-943N	<i>5 French</i>	February 1, 2005
9009-944	6 French	May 23, 1997
9009-944N	<i>6 French</i>	February 1, 2005
9009-945	7 French	May 23, 1997
9009-945N	<i>7 French</i>	February 1, 2005
9009-947	9 French	May 23, 1997
9009-947N	<i>9 French</i>	February 1, 2005
9009-949	11 French	May 23, 1997
9009-949N	<i>11 French</i>	February 1, 2005
9009-950	SUNDT™ Graduated Suction System, with 4 1/2" / 11.5 cm Non-Rotatable Tips, Universal Suction Handle 3" / 7.5 cm, 7 Suction Tips - diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr., 9 fr., 11 fr., Sterilization/Storage Case	May 23, 1997
Variable Suction Non-Rotatable Tips, 4 1/2" / 11.5 cm (for System #9009-950)		
9009-951	3 French	May 23, 1997
9009-952	4 French	May 23, 1997
9009-953	5 French	May 23, 1997
9009-954	6 French	May 23, 1997
9009-955	7 French	May 23, 1997

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Catalog Number	Product Name	CE Mark First Applied
9009-957	9 French	May 23, 1997
9009-959	11 French	May 23, 1997
9009-960	SUNDT™ Graduated Suction System with 5 1/4" / 13.5 cm Rotatable Tips, Universal And Suction Handle 3" / 7.5 cm, 7 Suction Tips diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr.,	May 23, 1997
9009-960N	9/fr., 11 fr., Sterilization/Storage Case	February 1, 2005
Variable Suction Rotatable Tips, 5 1/4" / 13.5 cm (for System #9009-960)		
9009-961	3 French	May 23, 1997
9009-961N	3 French	February 1, 2005
9009-962	4 French	May 23, 1997
9009-962N	4 French	February 1, 2005
9009-963	5 French	May 23, 1997
9009-963N	5 French	February 1, 2005
9009-964	6 French	May 23, 1997
9009-964N	6 French	February 1, 2005
9009-965	7 French	May 23, 1997
9009-965N	7 French	February 1, 2005
9009-967	9 French	May 23, 1997
9009-967N	9 French	February 1, 2005
9009-969	11 French	May 23, 1997
9009-969N	11 French	February 1, 2005
9009-970	SUNDT™ Graduated Suction System with 5 1/4" / 13.5 cm Non-Rotatable Tips, Universal Suction Handle 3" / 7.5 cm, 7 Suction Tips - diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr., 9/fr., 11 fr., Sterilization/Storage Case	May 23, 1997
Variable Suction Non-Rotatable Tips, 5 1/4" / 13.5 cm (for System #9009-970)		
9009-971	3 French	May 23, 1997
9009-972	4 French	May 23, 1997
9009-973	5 French	May 23, 1997
9009-974	6 French	May 23, 1997
9009-975	7 French	May 23, 1997
9009-977	9 French	May 23, 1997
9009-979	11 French	May 23, 1997
9009-980	SUNDT™ Graduated Suction System with 8 1/8" / 20.5 cm Rotatable Tips, Universal and Suction Handle 3" / 7.5 cm, 7 Suction Tips - diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr., 9 fr., 11 fr.,	May 23, 1997
9009-980N	Sterilization/Storage Case	February 1, 2005
Variable Suction Rotatable Tips, 7 7/8" / 19.8 cm (for System #9009-980)		
9009-981	3 French	May 23, 1997
9009-981N	3 French	February 1, 2005

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Catalog Number	Product Name	CE Mark First Applied
9009-982	4 French	May 23, 1997
9009-982N	4 French	February 1, 2005
9009-983	5 French	May 23, 1997
9009-983N	5 French	February 1, 2005
9009-984	6 French	May 23, 1997
9009-984N	6 French	February 1, 2005
9009-985	7 French	May 23, 1997
9009-985N	7 French	February 1, 2005
9009-987	9 French	May 23, 1997
9009-987N	9 French	February 1, 2005
9009-989	11 French	May 23, 1997
9009-989N	11 French	February 1, 2005
9009-990	SUNDT™ Graduated Suction System with 8 1/8" / 20.5 cm, Rotatable Tips, Universal Suction Handle 3" / 7.5 cm, 7 Suction Tips - diameters: 3 fr., 4 fr., 5 fr., 6 fr., 7 fr., 9 fr., 11 fr., Sterilization/Storage Case	May 23, 1997
Variable Suction Non-Rotatable Tips, 7 7/8" / 19.8 cm (for System #9009-990)		
9009-991	3 French	May 23, 1997
9009-992	4 French	May 23, 1997
9009-993	5 French	May 23, 1997
9009-994	6 French	May 23, 1997
9009-995	7 French	May 23, 1997
9009-997	9 French	May 23, 1997
9009-999	11 French	May 23, 1997

END OF PRODUCTLIST