

Products included in the certificate no: 41314263
Issued to: **Masimo Sweden AB**
Svärdvägen 15
SE-182 33 Danderyd
Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Gas Monitoring Devices					
<i>Mainstream multi-gas sensor</i>					
	IRMA CO2 Ref 200101	Ilb	No	-	*
	IRMA CO2 Bluepoint Ref 200104	Ilb	No	-	July 1, 2009
	IRMA CO2 Breas Ref 200105	Ilb	No	-	Mar 28, 2011
	IRMA CO2 LEMO Ref 200107	Ilb	No	36552	May 13, 2015
	IRMA AX+ Ref 200601	Ilb	No	-	*
	IRMA AX+ Bluepoint Ref 200604	Ilb	No	-	Sept 8, 2010
	IRMA AX+LEMO Ref 200607	Ilb	No	37061	May 13, 2015
	IRMA CO2 Spacelabs Ref 200101-SL	Ilb	No	-	May 16, 2018
<i>Sidestream multi-gas sensor</i>					
	ISA OR+ Ref 800401	Ilb	No	-	July 1, 2009
	ISA OR+ Root Ref 800406	Ilb	No	37061	Sep 4, 2014
	ISA AX+ Ref 800601	Ilb	No	-	July 1, 2009
	ISA AX+ Root Ref 800606	Ilb	No	37061	Sep 4, 2014
	ISA CO2 LEMO Ref 800107	Ilb	No	36552	June 22, 2015
	ISA OR+ LEMO Ref 800407	Ilb	No	37061	June 22, 2015
	ISA AX+ LEMO Ref 800607	Ilb	No	37061	June 22, 2015

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<i>Sampling line</i>					
Nomoline REF 108210 (Connected to ISA side- stream multi-gas sensor.)	Ila	No	-	July 1, 2009	
Nomoline Adapter REF 108220	Ila	No	-	Oct 11, 2011	
Nomoline Airway Adapter Set REF 108230	Ila	No	-	Oct 11, 2011	
NomoLine HH Multi-Patient Use Adapter Ref 3800	Ila	No	-	May 13, 2015	
NomoLine Adult/Pediatric Airway Adapter Set with Luer Ref 3801	Ila	No	-	May 13, 2015	
NomoLine Adult/Pediatric Airway Adapter Set 3m with Luer Ref 3802	Ila	No	-	May 13, 2015	
NomoLine Infant Airway Adapter Set with Luer Ref 3803	Ila	No	-	May 13, 2015	
NomoLine Adult Nasal CO2 Cannula with Luer Ref 3804	Ila	No	-	May 13, 2015	
NomoLine Pediatric Nasal CO2 Cannula with Luer Ref 3805	Ila	No	-	May 13, 2015	
NomoLine Infant Nasal CO2 Cannula with Luer Ref 3806	Ila	No	-	May 13, 2015	
NomoLine Adult Nasal CO2 Cannula with O2 and Luer Ref 3807	Ila	No	-	May 13, 2015	
NomoLine Pediatric Nasal CO2 Cannula with O2 and Luer Ref 3808	Ila	No	-	May 13, 2015	
NomoLine Adult Nasal/Oral CO2 Cannula with Luer Ref 3809	Ila	No	-	May 13, 2015	
NomoLine Pediatric Nasal/Oral CO2 Cannula with Luer Ref 3810	Ila	No	-	May 13, 2015	
NomoLine Adult Nasal/Oral CO2 Cannula with O2 and Luer Ref 3811	Ila	No	-	May 13, 2015	

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NomoLine Pediatric Nasal/Oral CO2 Cannula with O2 and Luer Ref 3812	Ila	No	-	May 13, 2015
NomoLine Adult Single Nasal Prong CO2 Cannula with Luer Ref 3813	Ila	No	-	May 13, 2015
NomoLine LH Adult/Pediatric Airway Adapter Set Ref 3814	Ila	No	-	May 13, 2015
NomoLine LH Adult/Pediatric Airway Adapter Set 3m Ref 3815	Ila	No	-	May 13, 2015
NomoLine LH Infant Airway Adapter Set Ref 3816	Ila	No	-	May 13, 2015
NomoLine LH Adult Nasal CO2 Cannula Ref3817	Ila	No	-	May 13, 2015
NomoLine LH Pediatric Nasal CO2 Cannula Ref 3818	Ila	No	-	May 13, 2015
NomoLine LH Infant Nasal CO2 Cannula Ref3819	Ila	No	-	May 13, 2015
NomoLine LH Adult Nasal CO2 Cannula with O2 Ref 3820	Ila	No	-	May 13, 2015
NomoLine LH Pediatric Nasal CO2 Cannula with O2 Ref 3821	Ila	No	-	May 13, 2015
NomoLine LH Adult Nasal/Oral CO2 Cannula Ref 3822	Ila	No	-	May 13, 2015
NomoLine LH Pediatric Nasal/Oral CO2 Cannula Ref 3823	Ila	No	-	May 13, 2015
NomoLine LH Adult Nasal/Oral CO2 Cannula with O2 Ref 3824	Ila	No	-	May 13, 2015
NomoLine LH Pediatric Nasal/Oral CO2 Cannula with O2 Ref 3825	Ila	No	-	May 13, 2015
NomoLine LH Adult Single Nasal Prong CO2 Cannula Ref 3826	Ila	No	-	May 13, 2015

NomoLine HH Adult/Pediatric Airway Adapter Set Ref 3827	Ila	No	-	May 13, 2015
NomoLine HH Adult/Pediatric Airway Adapter Set 3m Ref 3828	Ila	No	-	May 13, 2015
NomoLine HH Infant Airway Adapter Set Ref 3829	Ila	No	-	May 13, 2015
NomoLine HH Adult Nasal CO2 Cannula Ref 3830	Ila	No	-	May 13, 2015
NomoLine HH Pediatric Nasal CO2 Cannula Ref 3831	Ila	No	-	May 13, 2015
NomoLine HH Infant Nasal CO2 Cannula Ref 3832	Ila	No	-	May 13, 2015
NomoLine HH Adult Nasal CO2 Cannula with O2 Ref 3833	Ila	No	-	May 13, 2015
NomoLine HH Pediatric Nasal CO2 Cannula with O2 Ref 3834	Ila	No	-	May 13, 2015
NomoLine HH Adult Nasal/Oral CO2 Cannula Ref 3835	Ila	No	-	May 13, 2015
NomoLine HH Pediatric Nasal/Oral CO2 Cannula Ref 3836	Ila	No	-	May 13, 2015
NomoLine HH Adult Nasal/Oral CO2 Cannula with O2 Ref 3837	Ila	No	-	May 13, 2015
NomoLine HH Pediatric Nasal/Oral CO2 Cannula with O2 Ref 3838	Ila	No	-	May 13, 2015
NomoLine HH Adult Single Nasal Prong CO2 Cannula Ref 3839	Ila	No	-	May 13, 2015
NomoLine HH Infant/Neonatal Airway Adapter Set Ref 4367	Ila	No	45566	Mar 22,2018
NomoLine Infant/Neonatal Airway Adapter Set with Luer Ref 4368	Ila	No	45566	Mar 22.2018

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Intertek Semko AB

Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden

Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com

Registered in Sweden: No SE556024059901, Registered office: As address

NomoLine LH Infant/Neonatal Airway Adapter Set Ref 4369	Ila	No	45566	Mar 22, 2018
<i>Disposable airway adapter</i>				
IRMA Airway adapter (Adult/Pediatric) Ref 106220	Ila	No	-	*
IRMA Airway adapter Infant Ref 106260	Ila	No	-	*
EMMA Airway adapter (Adult/Pediatric) Ref 100620	Ila	No	-	*
EMMA Airway adapter Infant Ref 100660	Ila	No	-	*
<i>Mainstream emergency Capnometer</i>				
EMMA (kPa) Ref 605100	Ilb	No	-	*
EMMA (mmHg) Ref 605102	Ilb	No	-	*
EMMA Capnometer (kPa) Ref 606100	Ilb	No	36552	Oct 18, 2013
EMMA Capnometer (mmHg) Ref 606102	Ilb	No	36552	Oct 18, 2013
EMMA Bluetooth (kPa) Ref 655100	Ilb	No	36552	Mar 6, 2017
EMMA Bluetooth (mmHg) Ref 655102	Ilb	No	36552	Mar 6, 2017
<i>Sidestream Capnometer</i>				
ISA CO2 Ref 800101	Ilb	No	-	July 1, 2009
ISA CO2 ROOT Ref 800106	Ilb	No	-	April 19, 2013

* Product added before July 1, 2009

Date of Issue: May 16, 2018

Intertek Semko AB
Notified Body MDD



Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.
The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on
medical devices, with identification number 0413.