

# Konformitätserklärung / Declaration of Conformity

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## Vyairé Medical GmbH

Leibnizstrasse 7, 97204 Höchberg, Deutschland erklärt in alleiniger Verantwortung, dass die genannten Produkte auf die sich diese Erklärung bezieht, mit allen zutreffenden normativen Dokumenten übereinstimmen. Diese Produkte erfüllen die Anforderungen des Konformitätsbewertungsverfahrens nach Anhang II, Abschnitt 3 der Richtlinie 93/42/EWG und der Erweiterung 2007/47/EG und wurden unter Aufsicht der Benannten Stelle mit der Kennnummer 0123, TÜV Süd Product Service GmbH, Ridlerstraße 65, 80339 München, Deutschland, mit der CE-Kennzeichnung versehen.

## Vyairé Medical GmbH

Leibnizstrasse 7, 97204 Höchberg, Germany declares under sole responsibility that the below products to which this declaration relates is in conformity with all relevant normative documents.

This product is subjected to conformity assessment procedures set out in Annex II section 3 of directive 93/42/EEC as amended by 2007/47/EC and is CE marked under the supervision of Notified Body identification number 0123, TÜV Sued Product Service GmbH, Ridlerstrasse 65, 80339 Muenchen, Germany, and fulfils the obligation imposed by the quality system.

<b>DIMDI Registration Number</b>			<b>GMDN</b>	<b>UMDNS</b>
DE/CA59/209-2001	Handeichpumpe	Calibration Pump	60343	17-250
DE/CA59/037.04	Vyntus SPIRO	Vyntus SPIRO	13680	13-680
DE/CA59/037.04	Vyntus PNEUMO	Vyntus PNEUMO	13680	13-680
DE/CA59/128.98	Vyntus APS	Vyntus APS	35457	10-046
DE/CA59/1556/2019-R/Lg	Vyntus IOS	Vyntus IOS	35282	17-698
DE/CA59/110.98	Vyntus CPX	Vyntus CPX	36146	17-724
DE/CA59/205.2001	Vyntus ECG	Vyntus ECG	36367	11-411
DE/CA59/1503/2019-R/Lg	Vyntus WALK	Vyntus WALK	35447	17-667
DE/CA59/139.98	Vyntus BODY	Vyntus BODY	35242	13-059
DE/CA59/1556/2019-R/Lg	Vyntus ONE	Vyntus ONE	35282	17-698
DE/CA59/1555/2019-R/Lg	MicroCO	MicroCO Meter	35467	15-093
DE/CA59/037.04	Micro I	Micro I Spirometer	13680	13-680
DE/CA59/037.04	MicroLab	MicroLab	13680	13-680
DE/CA59/037.04	PulmoLife	PulmoLife	13680	13-680
DE/CA59/037.04	SpiroUSB	SpiroUSB	13680	13-680
DE/CA59/037.04	MicroRPM	MicroRPM	31318	13-680
DE/CA59/107.98	MicroPeak	MicroPeak	46872	15-965
DE/CA59/050.04	MicroGard II	MGII	60837	11-712
DE/CA59/050.04	Filter Kit MicroGard II	Filter Kit MicroGard II	60837	11-712
DE/CA64/JaegerToe/007	Mundstück	Mouthpiece	44545	17-824
DE/CA64/JaegerToe/007	Mundstück, ID 30, weich, blau	Disposable Mouthpiece, ID 30, soft, blue	44545	17-824
DE/CA59/1556/2019-R/Lg	JLAB 5.7x Software	JLAB SW	35282	10-984
DE/CA59/1556/2019-R/Lg	SentrySuite Software Version 2.7 and higher	SeS SW	35282	10-984
DE/CA59/1556/2019-R/Lg	SentryWEB SmartInterp Software	SeS WEB SmartInterp	35282	10-984
DE/CA59/1556/2019-R/Lg	Spirometry PC Software	SPCS	35282	10-984
DE/CA59/1502/2019-R/Lg	Vyntus Cart 3.0	Vyntus Cart 3.0	40596	10-635
	All Accessories are listed in the Appendix			

Höchberg, 2019-04-05



Detlef Grotheer  
Sicherheitsbeauftragter für Medizinprodukte/  
Safety Officer for Medical Products



Waldemar Fabry  
Manager Qualitätssteuerung/  
Quality Assurance Manager

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## Accessories for MasterScreen Body/Diff, MasterScreen PFT, MasterScreen IOS, APS PRO SA:

DIMDI Registration Number	Item Nr.	Description
DE/CA59/124.98	705048	Pneumotach plastic PT 36, heatable
DE/CA59/124.98	700096	Spare screen PT 36
DE/CA59/124.98	851243	O-Ring for plastic P-tube PT 36
DE/CA64/JaegerToe/001	706175N	Valve head for check valve
DE/CA64/JaegerToe/007	892102	Silicone mouthpiece for children
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, single use, 25 pieces
DE/CA64/JaegerToe/007	V-892894	Mouthpiece (disposable mouthpiece blue), 180 pieces
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pieces
DE/CA59/209.2001	720252	Manual calibration pump, 1 L
DE/CA59/209.2001	720254	Manual calibration pump, 3 L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm for manual calibration pump, 3 L
DE/CA64/00151871	852741	Silicone sleeve 115 mm
DE/CA64/00151871	852352	Elbow piece 45°
DE/CA64/00151871	706854	Elbow piece 45° with luer connector for drying tube ME
DE/CA64/00151871	852353	Adapter ID 30
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pad "foam material", 100 pieces
DE/CA64/00151869	S42101	Nose-clip disposable, 10 pieces
DE/CA64/00151869	S761889	Nose-clip disposable, 100 pieces
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard type IIB, 80 pcs.
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard type IIC, 80 pcs.
DE/CA64/00151871	V-861449	Silicone adapter "oval" for MicroGard IIB
DE/CA64/JaegerToe/009	V-852554	Drying Tube ME series 48 inch
DE/CA64/00151871	V-861732	Flow restrictor
Spare Part / Non Medical Device	706143	Absorber
Spare Part / Non Medical Device	892403	Sodalime "Sodasorb" 5 L
DE/CA59/050.04	706169	Bacteria filter set
DE/CA59/2095.1-2015/KE	852828	Breathing bags 20 L, 50 pieces
Spare Part / Non Medical Device	845513	Sealing plug gray, conical
DE/CA64/JaegerToe/009 + DE/CA64/00151871	706135	Flexible tube with coupling and extension
DE/CA64/00151871	705417	Flexible tube with elbow piece and extension
DE/CA64/00151871	706134	Double tube adapter
DE/CA64/00151871	706133	Adapter with 3 balloon valves
Spare Part / Non Medical Device	V-892075	Hygiene-Bundle for cross adapter
DE/CA64/00151871	705445	Cross connection adapter
DE/CA64/00151871	V-707290	RT-adapter

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DIMDI Registration Number	Item Nr.	Description
DE/CA64/00151871	706943	Connection adapter
DE/CA64/00151871	706943	Connection adapter
DE/CA64/00151871	705388	Y-adapter incl. terminal resistance
DE/CA59/124.98	705392	Reference resistance for IOS
DE/CA59/124.98	705368	Terminal resistance for IOS
DE/CA59/065.04	705094	IOS breathing mask for children (2-4 years)
DE/CA59/050.04	V-892020	APS AirLife® filter, 50 pcs.
DE/CA64/00151871	V-707307	APS connection block V2 for Sidestream
DE/CA59/128.98	V-707288	Nebulizer kit Sidestream® with 3 additional reusable nebulizer vessels and pressurized air tube
DE/CA59/128.98	V-892610	Nebulizer Sidestream reusable
DE/CA59/128.98	V-892608	Nebulizer Sidestream disposable, 50 pieces
DE/CA59/128.98	845579	Nebulizer end cap
DE/CA59/125.98	892137	Nose adapter, size 1, 50ea/pk
DE/CA59/125.98	892138	Nose adapter, size 2, 50ea/pk
DE/CA59/125.98	892139	Nose adapter, size 3, 50ea/pk
DE/CA64/JaegerToe/009	852195	Tube Connection with plug nipple for tube, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silicone tube, D 3x1.5mm
DE/CA64/JaegerToe/010	892533	Mix gas 0.265 % CO, 9.3 % He, 19 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters
DE/CA64/JaegerToe/010	892566	Mix gas 0.3 % CO, 0.3 % CH <sub>4</sub> , 0.3 % C <sub>2</sub> H <sub>2</sub> , 21 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters
DE/CA64/JaegerToe/010	892546	Mix gas 9.3 % He, 19 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters
DE/CA64/JaegerToe/010	892542	Gas cylinder 10 Liters
DE/CA64/JaegerToe/010	892501	Drug product O <sub>2</sub> for medicinal purposes, 10 Liters
DE/CA64/JaegerToe/010	892543	Gas cylinder 10 Liters for drug product O <sub>2</sub>

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### Accessories for MasterScope Body:

DIMDI Registration Number	Item Nr.	Description
DE/CA59/124.98	705048	Pneumotach plastic PT 36, heatable
DE/CA59/124.98	700096	Spare screen PT 36
DE/CA59/124.98	851243	O-Ring for plastic P-tube PT 36
DE/CA64/JaegerToe/001	706175N	Valve head for check valve
DE/CA64/JaegerToe/007	892102	Silicone mouthpiece for children
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, single use, 25 pieces
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pieces
DE/CA64/JaegerToe/007	V-892894	Mouthpiece (disposable mouthpiece blue), 180 pieces
DE/CA59/209.2001	720254	Manual calibration pump, 3 L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm for manual calibration pump, 3 L
DE/CA64/00151871	852352	Elbow piece 45°
DE/CA64/00151871	852353	Adapter ID 30
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pad "foam material", 100 pieces
DE/CA64/00151869	S42101	Nose-clip disposable, 10 pieces
DE/CA64/00151869	S761889	Nose-clip disposable, 100 pieces
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard type IIB, 80 pcs.
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard type IIC, 80 pcs.
DE/CA64/00151871	V-861449	Silicone adapter "oval" for MicroGard IIB
Spare Part / Non Medical Device	705043	Ground cable 4 mm <sup>2</sup>
Spare Part / Non Medical Device	845513	Plug grey, conic
Spare Part / Non Medical Device	845532	Plug grey, D30mm, PE, L30mm
DE/CA64/00151871	706943	Connection adapter (Body)
DE/CA59/125.98	892137	Nose adapter, size 1, 50ea/pk
DE/CA59/125.98	892138	Nose adapter, size 3, 50ea/pk
DE/CA59/125.98	892139	Nose adapter, size 3, 50ea/pk
DE/CA64/JaegerToe/009	852195	Tube Connection with plug nipple for tube, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silicone tube, D 3x1.5mm

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### Accessories for Oxycon Pro:

DIMDI Registration Number	Item Nr.	Description
	890008	Disinfectant „DESCOGEN I“ 1000g
DE/CA59/2094.1-2015/Ke	982084	ECG patient cable AHA with clamp, 10 leads
DE/CA59/2094.1-2015/Ke	V-98208	6 ECG patient cable IEC with clamp, 10 leads
DE/CA59/1558/2019-R/Lg	892802	Disposable gel electrodes for ECG, self-adhesive, for adults, 25 pcs.
DE/CA59/1558/2019-R/Lg	892205	Special disposable electrodes for stress ECG, 25 pcs.
DE/CA59/2095.1-2015/KE	852828	Breathing bag 20 L
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pads "foam material", 100 pcs.
DE/CA64/JaegerToe/007	982302	Mouthpiece "special"
DE/CA64/JaegerToe/007	705519	Mouthpiece "Free Flow", 12 pcs.
DE/CA59/065.04	982078	Breathing mask for children (incl. 3 headstraps)
DE/CA59/065.04	V-982188	Oro Nasal 7450 V2 Mask with headgear, size P
DE/CA59/065.04	V-982187	Oro Nasal 7450 V2 Mask with headgear, size ES
DE/CA59/065.04	V-982184	Oro Nasal 7450 V2 Mask with headgear, size S
DE/CA59/065.04	V-982185	Oro Nasal 7450 V2 Mask with headgear, size M
DE/CA59/065.04	V-982186	Oro Nasal 7450 V2 Mask with headgear, size L
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 Mask with headgear, size P (disposable, 18 EA/pack)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 Mask with headgear, size ES (disposable, 18 EA/pack)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 Mask with headgear, size S (disposable, 18 EA/pack)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 Mask with headgear, size M (disposable, 18 EA/pack)
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 Mask with headgear, size L (disposable, 18 EA/pack)
DE/CA64/00151871	V-982192	Mask adapter for DVT-volume-sensor (Triple V)
DE/CA64/JaegerToe/001	852972	Valve for "Combitox" mask
DE/CA59/119.98	982093	Triple V volume sensor complete for Oxycon Pro
DE/CA59/119.98	982094	Rotary flow sensor for Triple V
DE/CA64/JaegerToe/009	707004	Sample line (Twin Tube, 1 pc.)
DE/CA64/00151871	852352	Elbow piece 45°
DE/CA64/00151871	982053	Connection for Radiax valve
DE/CA64/JaegerToe/001	861717	Hans Rudolph T-valve (2700)
DE/CA64/JaegerToe/001	861719	Hans Rudolph Y-valve (2730)
Spare Part / Non Medical Device	861720	Adapter ring (for Hans Rudolph valve)
DE/CA64/00151871	707146	Adapter for High FIO2 bag (for Hans Rudolph valve)
DE/CA64/00151871	706823	Supply connection High FIO2
DE/CA64/JaegerToe/001	V-861721	Head Support for Hans Rudolph Y-valve 2730
DE/CA64/JaegerToe/010	343802	2 L steel cylinder with calibration gas incl. pressure reducer and connecting tube
DE/CA64/JaegerToe/010	892530	2 L steel cylinder with calibration gas (on return of an empty 2 L gas cylinder)
DE/CA64/JaegerToe/010	892568	0.38 L steel cylinder with calibration gas (on return of an empty 0.38 L gas cylinder)
DE/CA64/JaegerToe/010	V-892587	0.8 L steel cylinder with calibration gas (on return of an empty 0.8 L gas cylinder)
Spare Part / Non Medical Device	706547	Pressure reducer for calibration gas (1 pc.)
DE/CA64/JaegerToe/009	982096	Calibration gas tube (1 pc.)

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### Accessories for Oxycon Mobile:

DIMDI Registration Number	Item Nr.	Description
DE/CA59/065.04	982123	Head strap small (S) for breathing mask
DE/CA59/065.04	982124	Head strap medium (M) for breathing mask
DE/CA59/065.04	982125	Head strap large (L) for breathing mask
Disinfectant of the Shelve	141380	Disinfection set for Triple V
Disinfectant of the Shelve	890008	Disinfectant „DESCOGEN I“ 1000g
DE/CA64/JaegerToe/010	892568	Calibration gas in mini gas cylinder, 5% CO2, 16% O2, Rest N2, 0.38 L
DE/CA64/JaegerToe/010	892587	Calibration gas in mini gas cylinder, 5% CO2, 16% O2, Rest N2, 0.8 L
DE/CA59/1558/2019-R/Lg	892802	Disposable gel electrodes for ECG, self-adhesive, for adults, 25 pcs.
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pads "foam material", 100 pcs.
DE/CA64/JaegerToe/007	982302	Mouthpiece "special"
DE/CA64/JaegerToe/007	705519	Mouthpiece "Free Flow", 12 pcs.
DE/CA59/043.04	992578	Sticky tapes for Flex Sensor for adults, 25 pcs.
DE/CA59/065.04	982002	Breathing mask for adults "small" complete with head strap
DE/CA59/065.04	982003	Breathing mask for adults "large" complete with head strap
DE/CA59/065.04	982006	Breathing mask "Combitorx" complete with head strap
DE/CA59/065.04	982078	Breathing mask for children complete with head strap
Spare Part / Non Medical Device	923012	O2 sensor for CPX (UFO-130/2)
DE/CA59/043.04	992582	Earclip sensor for SpO2
DE/CA59/043.04	992506	SpO2 Flex Sensor incl. cable for adults
DE/CA59/119.98	707230	Triple V (volume sensor)
DE/CA59/119.98	982094	Rotary flow sensor for Triple V
DE/CA64/JaegerToe/009	707226	Sample line
Spare Part / Non Medical Device	980049	Polar belt (Set T61)
Spare Part / Non Medical Device	918274	USB cable (for connection of PCa to computer)
Spare Part / Non Medical Device	852948	Pressure reducer for mini gas cylinder
DE/CA64/JaegerToe/009	707224	Connection tube for mini gas cylinder, 0,5 m
Spare Part / Non Medical Device	923059	Earphone mono with 3.5 mm jack connector
Spare Part / Non Medical Device	853012	Vest size XL/XXL
DE/CA64/00151922	853013	Vest size S/M
DE/CA64/00151922	853014	Vest size M/L
DE/CA64/00151922	853015	Vest size L/XL
Spare Part / Non Medical Device	841500	Backpack
DE/CA59/130.98	806525	Lithium-ion battery 3.6 V
DE/CA59/2098.1-2015/Ke	996126	Charger for 2 lithium-ion batteries
DE/CA59/119.98	707231	Windshield for Triple V
Spare Part / Non Medical Device	966425	Flash Card
Spare Part / Non Medical Device	992289	Flash Card reader with USB port
Spare Part / Non Medical Device	922019	PCMCIA adapter for Flash Card
Spare Part / Non Medical Device	918315	Connection cable SBx-DEx (yellow)
DECA59/2101.1-2015/Ke	996124	Power supply for PCa
Spare Part / Non Medical Device	992295	Antenna for PCa or Dex
DE/CA59/130.98	343915	External battery pack
DE/CA64/JaegerToe/002	892194	Electrode cable L=90cm, red
DE/CA64/JaegerToe/002	892195	Electrode cable L=90cm, green
DE/CA64/JaegerToe/002	892196	Electrode cable L=90cm, black
DE/CA59/2094.1-2015/Ke	V-918204	ECG patient cable IEC with clamp, 20 cm, 10 leads
DE/CA64/JaegerToe/010	343802	2 L steel cylinder with calibration gas incl. pressure reducer and connecting tube
DE/CA64/JaegerToe/010	892530	2 L steel cylinder with calibration gas (on return of an empty 2 L gas cylinder)
DE/CA64/JaegerToe/010	892568	0.38 L steel cylinder with calibration gas (on return of an empty 0.38 L gas cylinder)
DE/CA64/JaegerToe/010	V-892587	0.8 L steel cylinder with calibration gas (on return of an empty 0.8 L gas cylinder)
Spare Part / Non Medical Device	706547	Pressure reducer for calibration gas (1 pc.)

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### Accessories for MasterScreen Baby Body:

DIMDI Registration Number	Item Nr.	Description
DE/CA59/124.98	V-707181	Paediatrics PT-S
DE/CA59/124.98	706286	Screen for Paediatrics PT-S
DE/CA59/124.98	V-707182	Shutter for Paediatrics PT-S
DE/CA59/209.2001	720320	Manual calibration pump 100mL
DE/CA64/00151871	706277	Silicon sleeve for manual calibration pump 100mL
DE/CA59/065.04	852712	Silikomed Baby mask size 0
DE/CA59/065.04	852713	Silikomed Baby mask size 1
Spare Part / Non Medical Device	705043	Ground cable 4qmm 4500 mm
DE/CA59/065.04	892805	Sealing material for masks
Spare Part / Non Medical Device	845562	Fixing cap black
DE/CA64/JaegerToe/009	706135	Light flexible tube
DE/CA64/00151922	852760	Squeeze Jacket size XXS
DE/CA64/00151922	852761	Squeeze Jacket size XS
DE/CA64/00151922	852762	Squeeze Jacket size S
Spare Part / Non Medical Device	852763	Breathing bladder 17/17cm
Spare Part / Non Medical Device	852764	Breathing bladder 21/21cm
Spare Part / Non Medical Device	845510	Plug, conical, grey
Spare Part / Non Medical Device	706546	Plug, slitted
Spare Part / Non Medical Device	845590	Fixing cap white
DE/CA64/00151869	892120	Nose clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose clip pad "foam material", 100 pcs.
DE/CA64/00151871	852352	Elbow 45°
DE/CA59/124.98	705048	Pneumotach plastic PT 36, heatable
DE/CA59/124.98	851243	O-ring for plastic p-tube PT 36
DE/CA59/124.98	700096	Spare screen PT 36
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, 25 pcs.
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pcs.
DE/CA59/209.2001	720254	Manual calibration syringe, 3L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm, for manual calibration syringe, 3 L
DE/CA64/00151871	852741	Silicone sleeve, 115 mm
DE/CA59/050.04	V-892384	MicroGard® IIC, 50 pcs.
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard® IIB with integrated mouthpiece, 50 pcs.
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard® type IIB, 80 pcs.
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard® type IIC, 80 pcs.
DE/CA64/00151871	V-861449	Silicone Adapter
DE/CA64/00151871	705388	Y-adapter incl. terminal resistance

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## Accessories for MasterScreen CPX:

DIMDI Registration Number	Item Nr.	Description
DE/CA59/124.98	705392	Reference resistance for IOS
DE/CA59/124.98	705368	Terminal resistance for IOS
DE/CA59/065.04	705094	IOS breathing mask for children (2-4 years)
Disinfectant of the Shelve	890008	Disinfectant „DESCOGEN I“ 1000g
DE/CA64/JaegerToe/010	892568	Calibration gas in mini gas cylinder, 5% CO2, 16% O2, Rest N2, 0.38 L
DE/CA64/JaegerToe/010	V-892587	Calibration gas in mini gas cylinder, 5% CO2, 16% O2, Rest N2, 0.8 L
DE/CA59/1558/2019-R/Lg	892802	Disposable gel electrodes for ECG, self-adhesive, for adults, (25 pcs.)
DE/CA59/1558/2019-R/Lg	892205	Special disposable electrodes for stress ECG (25 pcs.)
DE/CA59/2095.1-2015/KE	852828	Breathing bag 20 L PE-foil
DE/CA64/00151869	892120	Nose-clip
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pads "foam material"(single-use), 100 pcs.
DE/CA64/JaegerToe/007	982302	Mouthpiece "Spiro"
DE/CA64/JaegerToe/007	705519	Mouthpiece "Free Flow", 12 pcs.
DE/CA59/043.04	992578	Adult Flexi Wrap sticky tapes for Flex Sensor (25 pcs per package).
DE/CA59/065.04	982078	Breathing mask for children (incl. 3 headstraps)
DE/CA59/065.04	V-982188	Oro Nasal 7450 V2 Mask with headgear, size P
DE/CA59/065.04	V-982187	Oro Nasal 7450 V2 Mask with headgear, size ES
DE/CA59/065.04	V-982184	Oro Nasal 7450 V2 Mask with headgear, size S
DE/CA59/065.04	V-982185	Oro Nasal 7450 V2 Mask with headgear, size M
DE/CA59/065.04	V-982186	Oro Nasal 7450 V2 Mask with headgear, size L
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 Mask with headgear, size P (disposable, 18 EA/pack)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 Mask with headgear, size ES (disposable, 18 EA/pack)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 Mask with headgear, size S (disposable, 18 EA/pack)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 Mask with headgear, size M (disposable, 18 EA/pack)
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 Mask with headgear, size L (disposable, 18 EA/pack)
DE/CA64/00151871	V-982192	Mask adapter for DVT-volume-sensor (Triple V)
Spare Part / Non Medical Device	923012	O2 sensor for CPX (UFO-130/2)
DE/CA59/043.04	V-992528	SpO2 Reflectance Forehead Sensor 8000R
DE/CA59/043.04	V-992529	SpO2 Reflect Sensor Holder
DE/CA59/043.04	992582	Earclip sensor for SpO2 (Nonin)
DE/CA59/043.04	992506	SpO2 Flex Sensor incl. cable for adults (Nonin)
DE/CA59/119.98	707230	Triple V volume sensor
DE/CA59/119.98	982094	Volume sensor insert
DE/CA64/JaegerToe/009	707226	Sample line
Spare Part / Non Medical Device	980049	Polar sender-set T31
Spare Part / Non Medical Device	707236	Pressure reducer for mini gas cylinder
DE/CA64/JaegerToe/009	707224	Calibration tube L = 0.62 m for mini gas cylinder
DE/CA64/00151871	V-919383	Bend protection adapter
Spare Part / Non Medical Device	V-919382	Bend protection
DE/CA64/00151871	852352	Elbow piece 45°
DE/CA64/00151871	982053	Connection for Radiax valve
DE/CA64/JaegerToe/001	861717	Hans Rudolph T-valve (2700)
DE/CA64/JaegerToe/001	861719	Hans Rudolph Y-valve (2730)
DE/CA64/JaegerToe/001	V-861721	Head Support for Hans Rudolph Y-Valve 2730
Spare Part / Non Medical Device	861720	Adapter ring
DE/CA64/00151871	707146	Adapter for High FIO2 bag
DE/CA64/00151871	706823	Supply connection High FIO2
DE/CA59/2094.1-2015/Ke	V-982086	ECG patient cable IEC with clamp, 10 leads
DE/CA64/JaegerToe/010	343802	2 L steel cylinder with calibration gas incl. pressure reducer (706547) and connecting tube
DE/CA64/JaegerToe/010	892530	2 L steel cylinder with calibration gas (on return of an empty 2 L gas cylinder)

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### Accessories for MicroGard II, Filter Kit MicroGard II:

DIMDI Registration Number	Item Nr.	Description
DE/CA64/00151871	V-861449	Silikonadapter oval
DE/CA64/00151871	852740	Silikonmuffe (60mm)
DE/CA64/00151871	852353	Adapter ID 30

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Accessories for Vyntus SPIRO, Vyntus PNEUMO, Vyntus IOS, Vyntus APS, Vyntus CPX, Vyntus ECG, Vyntus WALK

DIMDI Registration Number	Item Nr.	Description
DE/CA59/124.98	705048	Pneumotach plastic PT 36, heatable
DE/CA59/124.98	709554	Pneumotach plastic PT 36, not heatable
DE/CA59/124.98	700096	Spare screen PT 36
DE/CA59/124.98	851243	O-Ring for plastic P-tube PT 36
DE/CA64/JaegerToe/001	706175	Valve head flap valve
DE/CA64/JaegerToe/007	892102	Silicone mouthpiece for children
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, single use, 25 pieces
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pieces
DE/CA64/JaegerToe/007	V-892894	Mouthpiece (disposable mouthpiece blue), 180 pieces
DE/CA59/209.2001	720252	Manual calibration syringe, 1 L
DE/CA59/209.2001	720254	Manual calibration syringe, 3 L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm for manual calibration syringe, 3 L
DE/CA64/00151871	852352	Elbow piece 45° 30 mm inner cone
DE/CA64/00151871	852353	Adapter ID 30
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pad "foam material", 100 pieces
DE/CA64/00151869	S42101	Nose-clip disposable, 10 pieces
DE/CA64/00151869	S761889	Nose-clip disposable, 100 pieces
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard type IIB, 80 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard type IIC, 80 pieces
DE/CA64/00151871	V-861449	Silicone Adapter
DE/CA64/00151871	705388	Y-adapter
DE/CA59/124.98	705392	Reference resistance for IOS
DE/CA59/124.98	705368	Terminal resistance for IOS
DE/CA59/065.04	705094	IOS breathing mask for children (2-4 years)
DE/CA59/050.04	V-892020	APS AirLife® filter, 50 pieces
DE/CA64/00151871	V-707307	APS connection block V2 for Sidestream
DE/CA59/128.98	V-707288	Nebulizer kit Sidestream® with 3 additional reusable nebulizer vessels and pressurized air tube
DE/CA59/128.98	V-892610	Nebulizer Sidestream reusable
DE/CA59/128.98	V-892608	Nebulizer Sidestream disposable, 50 pieces
DE/CA59/128.98	845579	Nebulizer end cap Medic-Aid
DE/CA59/125.98	892137	Nose adapter, size 1, 50ea/pk
DE/CA59/125.98	892138	Nose adapter, size 2, 50ea/pk
DE/CA59/125.98	892139	Nose adapter, size 3, 50ea/pk
Spare Part / Non Medical Device	852195	Plug nipple for tube, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silicone tube, D 3x1.5mm
DE/CA59/065.04	V-982186	CPET Mask 7450 V2, Size L, Complete
DE/CA59/065.04	V-982185	CPET Mask 7450 V2, Size M, Complete
DE/CA59/065.04	V-982184	CPET Mask 7450 V2, Size S, Complete
DE/CA59/065.04	V-982187	CPET Mask 7450 V2, Size XS, Complete
DE/CA59/065.04	V-982188	CPET Mask 7450 V2, Size Petite, Complete
DE/CA64/00151871	V-982192	Flexible mask adapter
DE/CA59/065.04	V-982181	Headgear Oro Nasal Mask 7450V2 Size L

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DIMDI Registration Number	Item Nr.	Description
DE/CA59/065.04	V-982180	Headgear Oro Nasal Mask 7450V2 Size M
DE/CA59/065.04	V-982189	Headgear Oro Nasal Mask 7450V2 Size ES and Petite
DE/CA59/065.04	V-982195	Brace Set, Size L, for CPET Mask 7450 V2
DE/CA59/065.04	V-982196	Brace Set, Size M, for CPET Mask 7450 V2
DE/CA59/065.04	V-982197	Brace Set, Size S, for CPET Mask 7450 V2
DE/CA59/065.04	V-982198	Brace Set, Size XS, for CPET Mask 7450 V2
DE/CA59/065.04	V-982199	Brace Set, Size Petite, for CPET Mask 7450 V2
DE/CA59/125.98	V-982179	Oro Nasal 6450 V2 DISP with HG Size L 18ea/bx
DE/CA59/125.98	V-982178	Oro Nasal 6450 V2 DISP with HG Size M 18ea/bx
DE/CA59/125.98	V-982177	Oro Nasal 6450 V2 DISP with HG Size S 18ea/bx
DE/CA59/125.98	V-982182	Oro Nasal 6450 V2 DISP with HG Size ES 18ea/bx
DE/CA59/125.98	V-982183	Oro Nasal 6450 V2 DISP with HG Size Petite 18ea/bx
DE/CA59/119.98	V-707326	Volume sensor DVT complete
DE/CA59/119.98	982094	Volume sensor insert
DE/CA64/00151871	V-861078	Adapter Jaeger cone for DVT Vyntus CPX
DE/CA64/JaegerToe/009	V-707327	Gas sample tube twin tube, 2.40 m
Spare Part / Non Medical Device	923015	O2 fuel cell
DE/CA59/043.04	992582	Ear clip sensor for SpO2
DE/CA59/043.04	992506	SpO2 Flex sensor with cable for adults
DE/CA59/043.04	992578	Adult Flexi Wrap adhesive tape for Flex Sensor (pack of 25 pcs.)
DE/CA59/043.04	V-992528	SpO2 Reflectance Forehead Sensor 8000R
DE/CA59/043.04	V-992529	SpO2 Reflect Sensor Holder
DE/CA64/JaegerToe/009	V-707309	Pressure reducer incl. connection tube for mini gas cylinder
DE/CA64/JaegerToe/010	V-892587	Calibration gas 5 % CO2, 16 % O2, Rest N2, 0.8L
DE/CA64/JaegerToe/010	V-892551	Gas cylinder 0.8 L for test gas
DE/CA59/1558/2019-R/Lg	992368	Disposable electrodes (Rest), 50 pieces
DE/CA59/1558/2019-R/Lg	892205	Disposable electrodes (Stress), 25 pieces
DE/CA59/130.98	806502	1.5V AA battery "Varta Industrial"
DE/CA59/130.98	V-806520	NiMH rechargeable battery 1.2 V AA ≥ 2500 mAh
DE/CA59/2098.1-2015/KE	V-996146	NiMH battery charger
Spare Part / Non Medical Device	V-841234	Bag for the Vyntus ECG, 25 pieces
DE/CA64/JaegerToe/001	V-861109	HR – valve 2730 complete
DE/CA59/2095.1-2015/KE	852828	Breathing bags 20 L (30 / pack)
DE/CA59/066.04	V-707332	DVT complete for High / Low FIO2
DE/CA64/00151871	707146	Hans-Rudolph inhaler adapter
DE/CA64/00151871	706823	Filling assembly for bag
DE/CA59/049.04	V-861721	Head fixation for High/Low FiO2
DE/CA64/00151871	707065	Coupling hose
DE/CA59/050.04	V-841191	Single patient hood kit 50 pieces (50 x MicroGard filter + 50 x foil)
DE/CA64/00151921	V-841182	Foil for Hood, pack of 50
DE/CA64/JaegerToe/009	V-821555	Canopy Tube
DE/CA64/00151871	706265	Adapter-large
DE/CA64/00151871	852351	Cone-adapter
DE/CA64/00151921	V-861108	Holder for Hood
DE/CA64/JaegerToe/001	V-707334	Jet-valve
DE/CA64/00151921	V-835490	Plug-in for Hood, pack of 2
DE/CA64/JaegerToe/010	343802 2	Liter steel cylinder with calibration gas incl. pressure reducer (706547) and connection tube
DE/CA64/JaegerToe/010	892530	Calibration gas 4.9 % - 6.2 % CO2, 14.5 % - 16 % O2, Rest N2, 2 L
DE/CA64/JaegerToe/010	892553	Gas cylinder 2 L for test gas
Disinfectant of the Shelve	890008	Disinfectant Type "Descogen® I", 1000 g

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### Accessories for Vyntus BODY

DIMDI Registration Number	Item Nr.	Description
DE/CA64/JaegerToe/007	892102	Silicone mouthpiece for children
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children
DE/CA64/JaegerToe/007	892100	Silicone mouthpiece
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, single use, 25 pieces
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pieces
DE/CA64/JaegerToe/007	V-892894	Mouthpiece (disposable mouthpiece blue), 180 pieces
DE/CA59/209.2001	720252	Manual calibration syringe, 1 L
DE/CA59/209.2001	720254	Manual calibration syringe, 3 L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm for manual calibration syringe, 3 L
DE/CA64/00151871	V-861449	Silicone Adapter
DE/CA64/00151871	852353	Adapter ID 30
DE/CA64/00151869	892120	Nose-clip "plastic"
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose-clip pad "foam material", 100 pieces
DE/CA64/00151869	S42101	Nose-clip disposable, 10 pieces
DE/CA64/00151869	S761889	Nose-clip disposable, 100 pieces
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard type IIB, 80 pieces
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard type IIC, 80 pieces
DE/CA59/050.04	V-892020	APS AirLife® filter, 50 pieces
DE/CA64/00151871	V-707307	APS connection block V2 for Sidestream
DE/CA59/128.98	V-707288	Nebulizer kit Sidestream® with 3 additional reusable nebulizer vessels and pressurized air tube
DE/CA59/128.98	V-892610	Nebulizer Sidestream reusable
DE/CA59/128.98	V-892608	Nebulizer Sidestream disposable, 50 pieces
DE/CA59/128.98	845579	Nebulizer end cap Medic-Aid
DE/CA59/119.98	V-707377	USS Module with adapter and prot. cover
DE/CA64/00151871	V-707380	USS MicroGard Adapter
Spare Part / Non Medical Device	V-707384	Cable port protective cover, 5 pieces
DE/CA59/066.04	V-707389	FPV block
DE/CA59/066.04	V-707388	FPV shutter mechanism
DE/CA64/JaegerToe/001	V-707390	FPV silicone valves, 5 pieces
DE/CA59/066.04	V-707397	FPV X-Ring Kit consists of 3 x X-ring and 1 x small rod
Disinfectant of the Shelve	V-707382	Automated disinfection pack
DE/CA59/119.98	V-707383	USS Module holder
DE/CA59/066.04	V-707393	FPV block holder
Disinfectant of the Shelve	V-707394	Disinfection tray insert
DE/CA64/00151871	V-707381	USS MicroGard Adapter for gas sampling
DE/CA64/JaegerToe/009	V-852554	Drying Tube ME series 48 inch
DE/CA64/JaegerToe/010	892566	Mix gas 0.3 % CO, 0.3 % CH <sub>4</sub> , 0.3 % C <sub>2</sub> H <sub>2</sub> , 21 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters
DE/CA64/JaegerToe/010	892542	Gas cylinder 10 Liters

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### Accessories for BabyCO, MicroCO, Smoke Check

DIMDI Registration Number	Item Nr.	Description
DE/CA64/JaegerToe/007	36-PSA1200	Paediatric Mouthpiece
DE/CA64/00151871	36-PSA2000	Mouthpiece Adaptor
DE/CA64/00151871	36-PSA1100	Paediatric Adaptor
DE/CA59/130.98	36-BAT1002	ALKALINE PP3 BATTERY
Spare Part / Non Medical Device	36-MEC1184	Calibration Tool
DE/CA64/JaegerToe/010	36-MCG020	Disposable Calibration Check Gas
Spare Part / Non Medical Device	36-MGA222	MicroFlow pressure reducer for Medican calibration gas canister with flow indicator
DE/CA64/00151871	36-MEC1007	22mm reducing connector for calibration
Spare Part / Non Medical Device	36-CAB1000	Interface Cable for PUMA Software
Disinfectant of the Shelf	36-SSC5000A	Perasafe Sterilizing Solution – 81g
DE/CA64/00151869	36-VOL2104	Nose clip
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip

### Accessories for MicroRPM

DIMDI Registration Number	Item Nr.	Description
DE/CA59/050.04	36-FIL6050	Bacterial Filter
DE/CA59/050.04	36-FIL6050A	Bacterial Filter and Adapter
DE/CA64/JaegerToe/007	36-MTH6410	Rubber Flanged Mouthpiece
DE/CA64/JaegerToe/001	36-ASS1221	Expiratory Pressure Valve
DE/CA64/JaegerToe/001	36-ASS1222	Inspiratory Pressure Valve
DE/CA59/125.98	36-NPROBE01	Extra Small Nasal Probes
DE/CA59/125.98	36-NPROBE02	Small Nasal Probes
DE/CA59/125.98	36-NPROBE03	Medium Nasal Probes
DE/CA59/125.98	36-NPROBE04	Large Nasal Probes
DE/CA64/00151871	36-ASS1091	Nasal Probe Adaptor
Spare Part / Non Medical Device	36-MEC1299	Calibration Srewdriver
DE/CA59/130.98	36-BAT1002	ALKALINE PP3 BATTERY
Disinfectant of the Shelf	36-SSC5000A	Perasafe Sterilizing Solution – 81g
DE/CA64/JaegerToe/010	36-ASS1234	Pressure Calibration Kit
Spare Part / Non Medical Device	36-CAB1000	Interface Cable for PUMA Software

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### Accessories for Micro I, MicroDiary, SpiroUSB, MicroLab, MicroLoop, PulmoLife

DIMDI Registration Number	Item Nr.	Description
DE/CA64/JaegerToe/007	36-PSA1000	Adult Mouthpiece
DE/CA64/JaegerToe/007	36-SST1250	Adult One Way Mouthpiece
DE/CA64/JaegerToe/007	36-SST1000	Adult One Way Mouthpiece
DE/CA64/JaegerToe/007	36-PSA2200	Universal Mouthpiece
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces
DE/CA64/00151871	36-MFA1010	MicroGard Filter Adaptor
DE/CA64/00151871	36-MFA1050	MicroGard Filter Adaptor
DE/CA64/JaegerToe/007	36-PSA1200	Paediatric Mouthpiece
DE/CA64/00151871	36-PSA1100	Paediatric Adaptor
Disinfectant of the Shelve	36-SSC5000A	Perasafe Sterilizing Solution – 81g
DE/CA64/00151869	36-VOL2104	Nose clip
DE/CA64/00151869	V-892895	Nose clip
DE/CA64/00151869	V-892900	Nose clip
DE/CA64/00151869	892121	Nose clip pad
DE/CA59/209.2001	36-SM2125	Calibration Pump
DE/CA64/00151871	36-MLD1621	Mouthpiece Adaptor
DE/CA59/130.98	36-BAT1043	Battery Pack (NiMH AA 2.4V, 1600mAh)
DE/CA59/122.98	36-PSU1017	5V DC 1.2A (GlobTek WR9QA1200USBNR-G2267)
Spare Part / Non Medical Device	36-PSU1012	Mains Adaptor
Spare Part / Non Medical Device	36-PSU1013	Mains Adaptor
DE/CA64/00151871	861427	Calibration syringe adapter
DE/CA64/00151871	36-CON1195	PSU Adaptor set – UK, Euro, USA, Australia
DE/CA64/00151871	V-861449	Silicone Adapter
DE/CA59/126.98	36-SPC1000	Spirometry PC Software
Spare Part / Non Medical Device	36-CAB1047	USB Extension cable
DE/CA59/2098.1-2015/Ke	36-ASS1041	SpiroUSB desktop stand
DE/CA59/119.98	36-TDX1043	Turbine Complete
DE/CA59/119.98	36-TDX1048	Turbine Complete
DE/CA59/119.98	36-TDX1050	Turbine Complete
Spare Part / Non Medical Device	36-CAB1098	USB A cable
Spare Part / Non Medical Device	36-CAB1048	USB Lead
Spare Part / Non Medical Device	36-CAB1049	USB Lead to Printer
Spare Part / Non Medical Device	36-PSA1600	Thermal Printer Paper
DE/CA59/2098.1-2015/Ke	36-ASS1244	MicroLoop Cradle
Spare Part / Non Medical Device	36-CAS1048	Pouch for PulmoLife

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## Accessories for Vyntus ONE

DIMDI Registration Number	Item Nr.	Description
DE/CA64/JaegerToe/007	892100	Mouthpiece Silicone SM25 (applied part, discontinued)
DE/CA64/JaegerToe/007	V-892235	Mouthpiece Silicone Adult, pack of 5 x 892100 (applied part)
DE/CA64/JaegerToe/007	892102	Mouthpiece Silicone Children (applied part, discontinued)
DE/CA64/JaegerToe/007	V-892230	Mouthpiece Silicone Children, pack of 5 x 892102 (applied part)
DE/CA64/JaegerToe/007	892103	Plastic mouthpiece, single use, 25 pieces (applied part)
DE/CA64/JaegerToe/007	S773470	Silicone mouthpiece FreeFlow™, 12 pieces (applied part)
DE/CA64/JaegerToe/007	V-892894	Mouthpiece (disposable mouthpiece blue), 180 pieces (applied part)
DE/CA59/209.2001	720252	Manual calibration syringe, 1 L (discontinued)
DE/CA59/209.2001	720254	Manual calibration syringe, 3 L
DE/CA64/00151871	852740	Silicone sleeve, 60 mm for manual calibration syringe, 3 L
DE/CA64/00151871	V-861449	Silicone adapter „Oval“ for MicroGard IIB
DE/CA64/00151871	852353	Adapter ID 30
DE/CA64/00151869	892120	Nose-clip "plastic"(applied part, discontinued)
DE/CA64/00151869	892121	Nose-clip pad "foam material", 100 pieces (applied part)
DE/CA64/00151869	S42101	Nose-clip disposable, 10 pieces (applied part, discontinued)
DE/CA64/00151869	S761889	Nose-clip disposable, 100 pieces (applied part, discontinued)
DE/CA64/00151869	V-892895	Nose-clip (reusable), 5 pieces (applied part)
DE/CA64/00151869	V-892900	Nose-clip (disposable), 10 pieces (applied part)
DE/CA59/050.04	V-892384	MicroGard IIC, 50 pieces (applied part)
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB with integrated mouthpiece, 50 pieces (applied part)
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filter kit MicroGard type IIB, 80 pieces (contains applied parts)
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filter kit MicroGard type IIC, 80 pieces (contains applied parts)
DE/CA59/119.98	V-707377	USS Module with adapter and protective cover
DE/CA64/00151871	V-707380	USS MicroGard Adapter
DE/CA64/00151871	V-707381	USS MicroGard Adapter for gas sampling
DE/CA64/JaegerToe/009	V-707722	Sample line Vyntus ONE
Spare Part / Non Medical Device	V-707384	Cable port protective cover, 5 pieces
DE/CA64/JaegerToe/001	V-707721	FPV block eDemand incl. 2 x silicone valve
DE/CA59/066.04	V-707744	FPV shutter mechanism c-shape
DE/CA64/JaegerToe/001	V-707390	FPV silicone valves, 5 pieces
DE/CA59/066.04	V-707741	Housing clamp FPV eDemand
DE/CA59/119.98	V-707383	USS Module holder
Disinfectant of the Shelve	V-707394	Disinfection tray insert
DE/CA64/JaegerToe/010	892566	Mix gas 0.3 % CO, 0.3 % CH <sub>4</sub> , 0.3 % C <sub>2</sub> H <sub>2</sub> , 21 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters (gas for diffusion measurement)
DE/CA64/JaegerToe/010	892566R	Medical mix gas 0.3 % CO, 0.3 % CH <sub>4</sub> , 0.3 % C <sub>2</sub> H <sub>2</sub> , 21 % O <sub>2</sub> , Rest N <sub>2</sub> , 10 Liters (gas for diffusion measurement - only for Germany)
DE/CA64/JaegerToe/010	892542	Gas cylinder 10 Liters (for gas 892533, 892566, 892566R, 892546)
DE/CA64/JaegerToe/010	892501	Drug product O <sub>2</sub> for medicinal purposes, 10 Liters
DE/CA64/JaegerToe/010	892543	Gas cylinder 10 Liters for drug product O <sub>2</sub> (for gas 892501)
DE/CA64/JaegerToe/010	V-892592	Vyntus ONE Calibration gas 16 % O <sub>2</sub> , 5 % CO <sub>2</sub> , 0.3 % CH <sub>4</sub> , 0.3 % CO, 0.3 % C <sub>2</sub> H <sub>2</sub> , Rest N <sub>2</sub> , 80 Litres
DE/CA64/JaegerToe/010	V-892495	Gas cylinder 0.5 Liters for calibration gas (for gas V-892592)
DE/CA59/125.98	892137	Nose adapter, size 1, 50ea/pk (applied part)
DE/CA59/125.98	892138	Nose adapter, size 2, 50ea/pk (applied part)
DE/CA59/125.98	892139	Nose adapter, size 3, 50ea/pk (applied part)
DE/CA59/065.04	852715	Face mask for Rhinomanometry (Rhino) (applied part)
DE/CA64/00151871	V-707723	Cone Adapter with hole (Rhino)
DE/CA64/00151871	V-708052	Connection set (consists of 852367, V-852039, 852635, and 852633)
DE/CA59/207.2001	705003	Esophagus Catheter Set, 5 pieces (applied part)
DE/CA59/119.98	V-707326	Volume sensor DVT (digital volume transducer) complete
DE/CA59/119.98	982094	Volume sensor insert

Art.-Nr./Part No.: V-785032 Rev. 04

# Konformitätserklärung / Declaration of Conformity

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DIMDI Registration Number	Item Nr.	Description
DE/CA59/119.98	V-707725	Volume sensor insert, single use
DE/CA64/00151871	V-861078	Adapter Jaeger cone for DVT Vyntus
Spare Part / Non Medical Device	923015	O2 fuel cell
DE/CA59/043.04	992582	Ear clip sensor for SpO2 (Nonin Model 8000Q2) (applied part)
Spare Part / Non Medical Device	V-841188	Calibration gas holder (0.8/0.38 L)
DE/CA64/JaegerToe/010	706183	Gas bottle wall mount
DE/CA59/043.04	992506	SpO2 Flex sensor with cable for adults (Nonin Model 8000J-3) (applied part)
DE/CA59/043.04	992578	Adult Flexi Wrap adhesive tape for Flex Sensor (pack of 25 pcs.) (Nonin Model 8000JFW) (applied part)
DE/CA59/043.04	V-992528	SpO2 Reflectance Forehead Sensor (Nonin Model 8000R) (applied part)
DE/CA59/043.04	V-992529	SpO2 Reflect Sensor Holder (Nonin Model 8000H) (applied part)
DE/CA59/043.04	V-992512	Nonin XPOD 3011 LP w. ODU
DE/CA59/065.04	V-982186	CPET Mask 7450 V2, Size L, Complete (applied part)
DE/CA59/065.04	V-982185	CPET Mask 7450 V2, Size M, Complete (applied part)
DE/CA59/065.04	V-982184	CPET Mask 7450 V2, Size S, Complete (applied part)
DE/CA59/065.04	V-982187	CPET Mask 7450 V2, Size XS, Complete (applied part)
DE/CA59/065.04	V-982188	CPET Mask 7450 V2, Size Petite, Complete (applied part)
DE/CA64/00151871	V-982192	Flexible mask adapter
DE/CA59/065.04	V-982181	Headgear Oro Nasal Mask 7450V2 Size L (applied part)
DE/CA59/065.04	V-982180	Headgear Oro Nasal Mask 7450V2 Size M (applied part)
DE/CA59/065.04	V-982189	Headgear Oro Nasal Mask 7450V2 Size ES and Petite (applied part)
DE/CA59/065.04	V-982195	Brace Set, Size L, for CPET Mask 7450 V2
DE/CA59/065.04	V-982196	Brace Set, Size M, for CPET Mask 7450 V2
DE/CA59/065.04	V-982197	Brace Set, Size S, for CPET Mask 7450 V2
DE/CA59/065.04	V-982198	Brace Set, Size XS, for CPET Mask 7450 V2
DE/CA59/065.04	V-982199	Brace Set, Size Petite, for CPET Mask 7450 V2
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 DISP with HG Size L 18ea/bx (disposable mask) (applied part)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 DISP with HG Size M 18ea/bx (disposable mask) (applied part)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 DISP with HG Size S 18ea/bx (disposable mask) (applied part)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 DISP with HG Size ES 18ea/bx (disposable mask) (applied part)
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 DISP with HG Size Petite 18ea/bx (disposable mask) (applied part)
DE/CA59/1558/2019-R/Lg	992368	Disposable electrodes (Rest), 50 pieces (applied part)
DE/CA59/1558/2019-R/Lg	892205	Disposable electrodes (Stress), 25 pieces (applied part)
DE/CA59/130.98	806502	1.5V AA battery "Varta Industrial"
DE/CA59/130.98	V-806520	NiMH rechargeable battery 1.2 V AA ≥ 2500 mAh
DE/CA59/2098.1-2015/KE	V-996146	NiMH battery charger
Spare Part / Non Medical Device	V-841234	Bag for the Vyntus ECG, 25 pieces (applied part)

## Atitikties deklaracija

Puslapis 1 iš 16

### Vyaire Medical GmbH

Leibnizstrasse 7, 97204 Hoechberg, Vokietija pagal savo atsakomybę skelbia, jog toliau nurodyti produktai, kuriems skirta ši deklaracija, atitinka visus susijusius normatyvinius dokumentus.

Šis produktas yra subjektas atitikties vertinimo procedūroms, nustatytoms direktyvos 93/42/EEB, papildytos 2007/47/EB, II priedo 3 skirsnyje ir pažymėtas CE stebint notifikuojančiai įstaiga, kurios identifikacinis numeris 0123, TUEV Sued Product Service GmbH, Rdilerstrasse 65, 80339 Muenchen, Vokietija, ir išpildo kokybės sistemos nustatytus įsipareigojimus.

<i>DIMDI registracijos numeris</i>		<i>GMDN</i>	<i>UMDNS</i>
DE/CA59/209-2001	Kalibracijos pompa	60343	17-250
DE/CA59/037.04	Vyntus SPIRO	13680	13-680
DE/CA59/037.04	Vyntus PNEUMO	13680	13-680
DE/CA59/128.98	Vyntus APS	35457	10-046
DE/CA59/1556/2019-R/Lg	Vyntus IOS	35282	17-698
DE/CA59/110.98	Vyntus CPX	36146	17-724
DE/CA59/205.2001	Vyntus ECG	36367	11-411
DE/CA59/1503/2019-R/Lg	Vyntus WALK	35447	17-667
DE/CA59/139.98	Vyntus BODY	35242	13-059
DE/CA59/1556/2019-R/Lg	Vyntus ONE	35282	17-698
DE/CA59/1555/2019-R/Lg	MicroCO matuoklis	35467	15-093
DE/CA59/037.04	Micro I spirometras	13680	13-680
DE/CA59/037.04	MicroLab	13680	13-680
DE/CA59/037.04	PulmoLife	13680	13-680
DE/CA59/037.04	SpiroUSB	13680	13-680
DE/CA59/037.04	MicroRPM	31318	13-680
DE/CA59/107.98	MicroPeak	46872	15-965
DE/CA59/050.04	MGII	60837	11-712
DE/CA59/050.04	Filter Kit MicroGard II	60837	11-712
DE/CA64/JaegerToe/007	Kandiklis	44545	17-824
DE/CA64/JaegerToe/007	Vienkartinis kandiklis, ID 30, minkštas, mėlynas	44545	17-824
DE/CA59/1556/2019-R/Lg	JLAB 5.7x programinė įranga	35282	10-984
DE/CA59/1556/2019-R/Lg	SeS SW programinė įranga Versija 2.7 ir aukštesnė	35282	10-984
DE/CA59/1556/2019-R/Lg	SeS WEB SmartInterp programinė įranga	35282	10-984
DE/CA59/1556/2019-R/Lg	Spirometrijos AK programinė įranga	35282	10-984
DE/CA59/1502/2019-R/Lg	Vyntus Cart 3.0	40596	10-635
	Visi priedai pateikiami prieduose		

Išversta teisingai pagal mano žinias ir įsitikinimus. Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.

Aš esu užtikrintas, kad lietuvių kalbos vertimas atitinka originalų dokumentą.



Vaidas Vilmantas (MB „Beikeris“, jm .k. 304539005)

Hoechberg, 2019-04-05

/parašas/

Detlef Grotheer

Saugumo pareigūnas medicinos produktams

/parašas/

Waldemar Fabry

Kokybės užtikrinimo vadovas

Produkto nr.: V-785032 Perž. 4

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## Atitikties deklaracija

Puslapis 2 iš 16

### MasterScreen Body / Diff, MasterScreen PFT, MasterScreen IOS, APS PRO SA priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/124.98	705048	Pneumatinis plastikas PT 36, kaitinamas
DE/CA59/124.98	700096	Atsarginis ekranas PT 36
DE/CA59/124.98	851243	O žiedas plastikiniam P mėgintuvėliui PT 36
DE/CA64/JaegerToe/001	706175N	Vožtuvo galvutė kontroliniam vožtuvui
DE/CA64/JaegerToe/007	892102	Silikoninis kandiklis vaikams
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, vienkartinis, 25 vienetai
DE/CA64/JaegerToe/007	V-892894	Kandiklis (vienkartinis mėlynas kandiklis), 180 vienetų
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlow™, 12 vienetų
DE/CA59/209.2001	720252	Rankinės kalibracijos siurblys, 1 L
DE/CA59/209.2001	720254	Rankinės kalibracijos siurblys, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm, skirta rankinės kalibracijos siurbliui, 3 L
DE/CA64/00151871	852741	Silikoninė mova 115 mm
DE/CA64/00151871	852352	Alkūnė 45°
DE/CA64/00151871	706854	Alkūnė 45° su luer jungtimi džiovavimo vamzdeliui ME
DE/CA64/00151871	852353	Adapteris ID 30
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos, 100 vienetų
DE/CA64/00151869	S42101	Vienkartinis nosies spaustukas, 10 vienetų
DE/CA64/00151869	S761889	Vienkartinis nosies spaustukas, 100 vienetų
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard type IIB, 80 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard type IIC, 80 vienetų
DE/CA64/00151871	V-861449	Silikoninis ovalus adapteris, skirtas MicroGard IIB
DE/CA64/JaegerToe/009	V-852554	Džiovinimo vamzdelis ME serijai, 48 colių
DE/CA64/00151871	V-861732	Srauto ribojimo įtaisas
Atsarginė dalis / ne medicinos prietaisas	706143	Sugėriklis
Atsarginė dalis / ne medicinos prietaisas	892403	Kalcio oksido ir natrio hidroksido mišinys „Sodasorb“, 5 L
DE/CA59/050.04	706169	Bakterinio filtro rinkinys
DE/CA59/2095.1-2015/KE	852828	Kvėpavimo maišai, 20 L, 50 vienetų
Atsarginė dalis / ne medicinos prietaisas	845513	Sandaravimo kaištis, pilkas, kūgio tipo
DE/CA64/JaegerToe/009 + DE/CA64/00151871	706135	Lankstus vamzdelis su mova ir išplėtimu
DE/CA64/00151871	705417	Lankstus vamzdelis su alkūne ir išplėtimu
DE/CA64/00151871	706134	Dvigubo vamzdelio adapteris
DE/CA64/00151871	706133	Adapteris su 3 baliono tipo vožtuvais
Atsarginė dalis / ne medicinos prietaisas	V-892075	Kryžminio adapterio higienos paketas
DE/CA64/00151871	705445	Kryžminės jungties adapteris
DE/CA64/00151871	V-707290	RT adapteris

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## Atitikties deklaracija

Puslapis 3 iš 16

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA64/00151871	706943	Jungties adapteris
DE/CA64/00151871	706943	Jungties adapteris
DE/CA64/00151871	705388	Y adapteris, įskaitant šiluminį atsparumą
DE/CA59/124.98	705392	Kontrolinis atsparumas, skirtas IOS
DE/CA59/124.98	705368	Šiluminis atsparumas, skirtas IOS
DE/CA59/065.04	705094	IOS kvėpavimo kaukė vaikams (2-4 metų amžiui)
DE/CA59/050.04	V-892020	APS AirLife® filtras, 50 vienetų
DE/CA64/00151871	V-707307	APS jungties blokas V2 šoniniam srautui
DE/CA59/128.98	V-707288	Purkštuvo rinkinys Sidestream® su 3 papildomais daugkartiniais purkštuvo indais ir suslėgto oro vamzdeliu
DE/CA59/128.98	V-892610	Purkštuvo šoninis srautas, daugkartinis
DE/CA59/128.98	V-892608	Purkštuvo šoninis srautas, vienkartinis, 50 vienetų
DE/CA59/128.98	845579	Purkštuvo galo dangtelis
DE/CA59/125.98	892137	Nosies adapteris, 1 dydis, 50 vienetų / dėžėje
DE/CA59/125.98	892138	Nosies adapteris, 2 dydis, 50 vienetų / dėžėje
DE/CA59/125.98	892139	Nosies adapteris, 3 dydis, 50 vienetų / dėžėje
DE/CA64/JaegerToe/009	852195	Vamzdelio jungtis su kištuko nipeliu vamzdeliui, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silikoninis vamzdelis, diametras 3x1.5 mm
DE/CA64/JaegerToe/010	892533	Dujų mišinys 0.265 % CO, 9.3 % He, 19 % O2, likusios N2, 10 litrų
DE/CA64/JaegerToe/010	892566	Dujų mišinys 0.3 % CO, 0.3 % CH4, 0.3 % C2H2, 21 % O2, likusios N2, 10 litrų
DE/CA64/JaegerToe/010	892546	Dujų mišinys 9.3 % He, 19 % O2, likusios N2, 10 litrų
DE/CA64/JaegerToe/010	892542	Dujų cilindras, 10 litrų
DE/CA64/JaegerToe/010	892501	Medikamentinis produktas O2 medicininiam tikslams, 10 litrų
DE/CA64/JaegerToe/010	892543	Dujų cilindras, 10 litrų medikamentiniam produktui O2

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## Atitikties deklaracija

Puslapis 4 iš 16

### MasterScreen Body priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/124.98	705048	Pneumatinis plastikas PT 36, kaitinamas
DE/CA59/124.98	700096	Atsarginis ekranas PT 36
DE/CA59/124.98	851243	O žiedas plastikiniam P mėgintuvėliui PT 36
DE/CA64/JaegerToe/001	706175N	Vožtuvo galvutė kontroliniam vožtuvui
DE/CA64/JaegerToe/007	892102	Silikoninis kandiklis vaikams
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, vienkartinis, 25 vienetai
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlow™, 12 vienetai
DE/CA64/JaegerToe/007	V-892894	Kandiklis (vienkartinis mėlynas kandiklis), 180 vienetai
DE/CA59/209.2001	720254	Rankinės kalibracijos siurblys, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm, skirta rankinės kalibracijos siurbliui, 3 L
DE/CA64/00151871	852352	Alkūnė 45°
DE/CA64/00151871	852353	Adapteris ID 30
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putas, 100 vienetai
DE/CA64/00151869	S42101	Vienkartinis nosies spaustukas, 10 vienetai
DE/CA64/00151869	S761889	Vienkartinis nosies spaustukas, 100 vienetai
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard type IIB, 80 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard type IIC, 80 vienetai
DE/CA64/00151871	V-861449	Silikoninis ovalus adapteris, skirtas MicroGard IIB
Atsarginė dalis / ne medicinos prietaisas	705043	Įžeminimo laidas 4 mm <sup>2</sup>
Atsarginė dalis / ne medicinos prietaisas	845513	Pilkas kištukas, kūgio formos
Atsarginė dalis / ne medicinos prietaisas	845532	Pilkas kištukas, diametras 30mm, PE, ilgis 30mm
DE/CA64/00151871	706943	Jungties adapteris (Body)
DE/CA59/125.98	892137	Nosies adapteris, 1 dydis, 50 vienetai / dėžėje
DE/CA59/125.98	892138	Nosies adapteris, 3 dydis, 50 vienetai / dėžėje
DE/CA59/125.98	892139	Nosies adapteris, 3 dydis, 50 vienetai / dėžėje
DE/CA64/JaegerToe/009	852195	Vamzdelio jungtis su kištuko nipeliu vamzdeliui, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silikoninis vamzdelis, diametras 3x1.5 mm

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## Atitikties deklaracija

Puslapis 5 iš 16

### Oxycon Pro priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
Disinfectant of the Shelve	890008	Dezinfektantas „DESCOGEN I“ 1000g
DE/CA59/2094.1-2015/Ke	982084	EKG paciento laidas AHA su spaustuku, 10 jungiamųjų laidų
DE/CA59/2094.1-2015/Ke	V-98208	6 EKG paciento laidas IEC su spaustuku, 10 jungiamųjų laidų
DE/CA59/1558/2019-R/Lg	892802	Vienkartiniai geliniai elektrodai, skirti EKG, savaimė limpantys, suaugusiems, 25 vienetai
DE/CA59/1558/2019-R/Lg	892205	Specialūs vienkartiniai elektrodai stresiniam EKG, 25 vnt.
DE/CA59/2095.1-2015/KE	852828	Kvėpavimo maišas, 20 L
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos, 100 vienetų
DE/CA64/JaegerToe/007	982302	Specialus kandiklis
DE/CA64/JaegerToe/007	705519	Laisvo srauto kandiklis, 12 vienetų
DE/CA59/065.04	982078	Kvėpavimo kaukė vaikui (su 3 galvos juostomis)
DE/CA59/065.04	V-982188	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis P
DE/CA59/065.04	V-982187	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis ES
DE/CA59/065.04	V-982184	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis S
DE/CA59/065.04	V-982185	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis M
DE/CA59/065.04	V-982186	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis L
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis P (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis ES (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis S (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis M (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis L (vienkartinė, 18 vienetų / pakuotėje)
DE/CA64/00151871	V-982192	Kaukės adapteris DVT tūrio davikliui (trigubas V)
DE/CA64/JaegerToe/001	852972	Vožtuvas Combitor kaukei
DE/CA59/119.98	982093	Trigubo V tūrio daviklis, pilnas, skirtas Oxycon Pro
DE/CA59/119.98	982094	Rotacinis srauto daviklis trigubam V
DE/CA64/JaegerToe/009	707004	Mėginio linija (dvigubas vamzdelis, 1 vienetas)
DE/CA64/00151871	852352	Alkūnė 45°
DE/CA64/00151871	982053	Jungtis Radiax vožtuvui
DE/CA64/JaegerToe/001	861717	Hans Rudolph T-vožtuvas (2700)
DE/CA64/JaegerToe/001	861719	Hans Rudolph Y-vožtuvas (2730)
Atsarginė dalis / ne medicinos prietaisas	861720	Adapterio žiedas (Hans Rudolph vožtuvui)
DE/CA64/00151871	707146	Adapteris aukšto FIO2 maišui (Hans Rudolph vožtuvui)
DE/CA64/00151871	706823	Tiekimo jungtis aukštam FIO2
DE/CA64/JaegerToe/001	V-861721	Galvos atrama Hans Rudolph Y-vožtuvui 2730
DE/CA64/JaegerToe/010	343802	2 L plieninis cilindras su kalibravimo dujomis, įskaitant slėgio reduktorių ir jungiamąjį vamzdelį
DE/CA64/JaegerToe/010	892530	2 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 2 L dujų cilindą)
DE/CA64/JaegerToe/010	892568	0.38 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 0.38 L dujų cilindą)
DE/CA64/JaegerToe/010	V-892587	0.8 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 0.8 L dujų cilindą)
Atsarginė dalis / ne medicinos prietaisas	706547	Slėgio reduktorius kalibravimo dujoms (1 vienetas)
DE/CA64/JaegerToe/009	982096	Kalibravimo dujų vamzdelis (1 vienetas)

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## Atitikties deklaracija

Puslapis 6 iš 16

### Oxycon Mobile priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/065.04	982123	Maža galvos juosta (S) kvėpavimo kaukei
DE/CA59/065.04	982124	Vidutinė galvos juosta (M) kvėpavimo kaukei
DE/CA59/065.04	982125	Didelė galvos juosta (L) kvėpavimo kaukei
Disinfectant of the Shelve	141380	Dezinfekavimo rinkinys trigubam V
Disinfectant of the Shelve	890008	Dezinfektantas „DESCOGEN I“ 1000g
DE/CA64/JaegerToe/010	892568	Kalibravimo dujos mini dujų cilindre, 5% CO2, 16% O2, likusios N2, 0.38 L
DE/CA64/JaegerToe/010	892587	Kalibravimo dujos mini dujų cilindre, 5% CO2, 16% O2, likusios N2, 0.8 L
DE/CA59/1558/2019-R/Lg	892802	Vienkartiniai geliniai elektrodai, skirti EKG, savaimė limpantys, suaugusiems, 25 vienetai
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos, 100 vienetų
DE/CA64/JaegerToe/007	982302	Specialus kandiklis
DE/CA64/JaegerToe/007	705519	Laisvo srauto kandiklis, 12 vienetų
DE/CA59/043.04	992578	Lipnios juostos lankščiui davikliui suaugusiems, 25 vienetai
DE/CA59/065.04	982002	Kvėpavimo kaukė suaugusiems (maža), su galvos juosta
DE/CA59/065.04	982003	Kvėpavimo kaukė suaugusiems (didelė), su galvos juosta
DE/CA59/065.04	982006	Kvėpavimo kaukė Combitox, su galvos juosta
DE/CA59/065.04	982078	Kvėpavimo kaukė vaikams su galvos juosta
Atsarginė dalis / ne medicinos prietaisas	923012	O2 daviklis, skirtas CPX (UFO-130/2)
DE/CA59/043.04	992582	Ausies spaustuko daviklis, skirtas SpO2
DE/CA59/043.04	992506	SpO2 lankstus daviklis su laidu pacientams
DE/CA59/119.98	707230	Trigubas V (tūrio daviklis)
DE/CA59/119.98	982094	Rotacinis srauto daviklis trigubam V
DE/CA64/JaegerToe/009	707226	Mėgimio linija
Atsarginė dalis / ne medicinos prietaisas	980049	Polar diržas (rinkinys T61)
Atsarginė dalis / ne medicinos prietaisas	918274	USB laidas (PCa jungčiai į kompiuterį)
Atsarginė dalis / ne medicinos prietaisas	852948	Slėgio reduktorius mini dujų cilindriui
DE/CA64/JaegerToe/009	707224	Jungiamasis vamzdelis mini dujų cilindriui, 0,5 m
Atsarginė dalis / ne medicinos prietaisas	923059	Mono ausinės su 3.5 mm lizdo jungtimi
Atsarginė dalis / ne medicinos prietaisas	853012	Liemenė, dydis XL/XXL
DE/CA64/00151922	853013	Liemenė, dydis S/M
DE/CA64/00151922	853014	Liemenė, dydis M/L
DE/CA64/00151922	853015	Liemenė, dydis L/XL
Atsarginė dalis / ne medicinos prietaisas	841500	Kuprinė
DE/CA59/130.98	806525	Ličio jonų baterija, 3,6 V
DE/CA59/2098.1-2015/Ke	996126	Įkroviklis 2 ličio jonų baterijoms
DE/CA59/119.98	707231	Priekini stiklas trigubam V
Atsarginė dalis / ne medicinos prietaisas	966425	Flash Card
Atsarginė dalis / ne medicinos prietaisas	992289	Flash Card nuskaitymo įrenginys su USB jungtimi
Atsarginė dalis / ne medicinos prietaisas	922019	PCMCIA adapteris, skirtas Flash Card
Atsarginė dalis / ne medicinos prietaisas	918315	Jungties laidas SBx-DEx (geltonas)
DECA59/2101.1-2015/Ke	996124	Galios tiekimas, skirtas PCa
Atsarginė dalis / ne medicinos prietaisas	992295	Antena, skirta PCa ar Dex
DE/CA59/130.98	343915	Išorinės baterijos pakuotė
DE/CA64/JaegerToe/002	892194	Elektrodo laidas L=90cm, raudonas
DE/CA64/JaegerToe/002	892195	Elektrodo laidas L=90cm, žalias
DE/CA64/JaegerToe/002	892196	Elektrodo laidas L=90cm, juodas
DE/CA59/2094.1-2015/Ke	V-918204	EKG paciento laidas IEC su spaustuku, 20 cm, 10 jungiamųjų laidų
DE/CA64/JaegerToe/010	343802	2 L plieninis cilindras su kalibravimo dujomis, įskaitant slėgio reduktorių ir jungiamąjį vamzdelį
DE/CA64/JaegerToe/010	892530	2 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 2 L dujų cilindrą)
DE/CA64/JaegerToe/010	892568	0.38 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 0.38 L dujų cilindrą)
DE/CA64/JaegerToe/010	V-892587	0.8 L plieninis cilindras su kalibravimo dujomis (grąžinant tuščią 0.8 L dujų cilindrą)
Atsarginė dalis / ne medicinos prietaisas	706547	Slėgio reduktorius kalibravimo dujoms (1 vienetas)

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## Atitikties deklaracija

Puslapis 7 iš 16

### MasterScreen Baby Body priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/124.98	V-707181	Pediatrijos PT-S
DE/CA59/124.98	706286	Ekranas pediatrijos PT-S
DE/CA59/124.98	V-707182	Užraktas pediatrijos PT-S
DE/CA59/209.2001	720320	Rankinės kalibracijos siurblys 100mL
DE/CA64/00151871	706277	Silikoninė mova rankinės kalibracijos siurbliui, 100 mL
DE/CA59/065.04	852712	Silikomed Kūdikių kaukė, dydis 0
DE/CA59/065.04	852713	Silikomed Kūdikių kaukė, dydis 1
Atsarginė dalis / ne medicinos prietaisas	705043	Ižeminimo laidas 4qmm 4500 mm
DE/CA59/065.04	892805	Sandaravimo medžiaga kaukėms
Atsarginė dalis / ne medicinos prietaisas	845562	Fiksuojantis juodas dangtelis
DE/CA64/JaegerToe/009	706135	Lengvas lankstus vamzdelis
DE/CA64/00151922	852760	Squeeze Jacket, dydis XXS
DE/CA64/00151922	852761	Squeeze Jacket, dydis XS
DE/CA64/00151922	852762	Squeeze Jacket, dydis S
Atsarginė dalis / ne medicinos prietaisas	852763	Kvėpavimo pūslė 17/17cm
Atsarginė dalis / ne medicinos prietaisas	852764	Kvėpavimo pūslė 21/21cm
Atsarginė dalis / ne medicinos prietaisas	845510	Kištukas, kūgio formos, pilkas
Atsarginė dalis / ne medicinos prietaisas	706546	Kištukas, su išpjova
Atsarginė dalis / ne medicinos prietaisas	845590	Fiksuojantis baltas dangtelis
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos, 100 vienetų
DE/CA64/00151871	852352	Elbow 45°
DE/CA59/124.98	705048	Pneumatinis plastikas PT 36, kaitinamas
DE/CA59/124.98	851243	O žiedas plastikiniam P mėgintuvėliui PT 36
DE/CA59/124.98	700096	Atsarginis ekranas PT 36
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, 25 vienetai
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlow™, 12 vienetų
DE/CA59/209.2001	720254	Rankinės kalibracijos švirkštas, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm, rankinės kalibracijos švirkštui, 3 L
DE/CA64/00151871	852741	Silikoninė mova, 115 mm
DE/CA59/050.04	V-892384	MicroGard® IIC, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard® IIB su integruotu kandikliu, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard® type IIB, 80 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard® type IIC, 80 vienetų
DE/CA64/00151871	V-861449	Silikoninis adapteris
DE/CA64/00151871	705388	Y adapteris, įskaitant šiluminį atsparumą

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## Atitikties deklaracija

Puslapis 8 iš 16

### MasterScreen CPX priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/124.98	705392	Kontrolinis atsparumas, skirtas IOS
DE/CA59/124.98	705368	Šiluminis atsparumas, skirtas IOS
DE/CA59/065.04	705094	IOS kvėpavimo kaukė vaikams (2-4 metų amžiui)
Disinfectant of the Shelve	890008	Dezinfektantas „DESCOGEN I“ 1000g
DE/CA64/JaegerToe/010	892568	Kalibravimo dujos mini dujų cilindre, 5% CO <sub>2</sub> , 16% O <sub>2</sub> , likusios N <sub>2</sub> , 0.38 L
DE/CA64/JaegerToe/010	V-892587	Kalibravimo dujos mini dujų cilindre, 5% CO <sub>2</sub> , 16% O <sub>2</sub> , likusios N <sub>2</sub> , 0.8 L
DE/CA59/1558/2019-R/Lg	892802	Vienkartiniai gelio elektrodai, skirti EKG, savaimė limpantys, suaugusiems, (25 vienetai)
DE/CA59/1558/2019-R/Lg	892205	Specialūs vienkartiniai elektrodai stresiniam EKG (25 vienetai)
DE/CA59/2095.1-2015/KE	852828	Kvėpavimo maišas, 20 L PE-folija
DE/CA64/00151869	892120	Nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos (vienkartinis), 100 vienetų
DE/CA64/JaegerToe/007	982302	Kandiklis Spiro
DE/CA64/JaegerToe/007	705519	Laisvo srauto kandiklis, 12 vienetų
DE/CA59/043.04	992578	Suaugusių Flexi Wrap lipnios juostos, skirtos lanksčiam davikliui (25 vienetai pakuotėje)
DE/CA59/065.04	982078	Kvėpavimo kaukė vaikui (su 3 galvos juostomis)
DE/CA59/065.04	V-982188	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis P
DE/CA59/065.04	V-982187	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis ES
DE/CA59/065.04	V-982184	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis S
DE/CA59/065.04	V-982185	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis M
DE/CA59/065.04	V-982186	Oro Nasal 7450 V2 kaukė su galvos įranga, dydis L
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis P (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis ES (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis S (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis M (vienkartinė, 18 vienetų / pakuotėje)
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 kaukė su galvos įranga, dydis L (vienkartinė, 18 vienetų / pakuotėje)
DE/CA64/00151871	V-982192	Kaukės adapteris DVT tūrio davikliui (trigubas V)
Atsarginė dalis / ne medicinos prietaisas	923012	O <sub>2</sub> daviklis, skirtas CPX (UFO-130/2)
DE/CA59/043.04	V-992528	SpO <sub>2</sub> atspindėjimo kaktos daviklis 8000R
DE/CA59/043.04	V-992529	SpO <sub>2</sub> atspindėjimo daviklio laikiklis
DE/CA59/043.04	992582	Ausies spaustuko daviklis, skirtas SpO <sub>2</sub> (Nonin)
DE/CA59/043.04	992506	SpO <sub>2</sub> lankstus daviklis su laidu pacientams (Nonin)
DE/CA59/119.98	707230	Trigubo V tūrio daviklis
DE/CA59/119.98	982094	Tūrio daviklio įdėklas
DE/CA64/JaegerToe/009	707226	Mėginio linija
Atsarginė dalis / ne medicinos prietaisas	980049	Polar siuntėjo rinkinys T31
Atsarginė dalis / ne medicinos prietaisas	707236	Slėgio reduktorius mini dujų cilindriui
DE/CA64/JaegerToe/009	707224	Kalibravimo vamzdelis L = 0.62 m mini dujų cilindriui
DE/CA64/00151871	V-919383	Linkimo apsaugos adapteris
Atsarginė dalis / ne medicinos prietaisas	V-919382	Linkimo apsauga
DE/CA64/00151871	852352	Alkūnė 45°
DE/CA64/00151871	982053	Jungtis Radiax vožtuvui
DE/CA64/JaegerToe/001	861717	Hans Rudolph T-vožtuvas (2700)
DE/CA64/JaegerToe/001	861719	Hans Rudolph Y-vožtuvas (2730)
DE/CA64/JaegerToe/001	V-861721	Galvos atrama Hans Rudolph Y-vožtuvui 2730
Atsarginė dalis / ne medicinos prietaisas	861720	Adapterio žiedas
DE/CA64/00151871	707146	Adapteris aukšto FIO <sub>2</sub> maišui
DE/CA64/00151871	706823	Tiekimo jungtis aukštam FIO <sub>2</sub>
DE/CA59/2094.1-2015/Ke	V-982086	EKG paciento laidas IEC su spaustuku, 10 jungiamųjų laidų
DE/CA64/JaegerToe/010	343802	2 L plieninis cilindras su kalibravimo dujomis, įskaitant slėgio reduktorių (706547) ir jungiamąsias vamzdelis
DE/CA64/JaegerToe/010	892530	2 L plieninis cilindras su kalibravimo dujomis (gražinant tuščią 2 L dujų cilindrą)

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**Atitikties deklaracija**

Puslapis 9 iš 16

**MicroGard II, filtro rinkinio MicroGard II priedai:**

<b>DIMDI registracijos numeris</b>	<b>Produkto numeris</b>	<b>Apibūdinimas</b>
DE/CA64/00151871	V-861449	Silikoninis ovalus adapteris
DE/CA64/00151871	852740	Silikonmuffe (60mm)
DE/CA64/00151871	852353	Adapteris ID 30

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## Atitikties deklaracija

Puslapis 10 iš 16

Vyntus SPIRO, Vyntus PNEUMO, Vyntus IOS, Vyntus APS, Vyntus CPX, Vyntus ECG, Vyntus WALK priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/124.98	705048	Pneumatinis plastikas PT 36, kaitinamas
DE/CA59/124.98	709554	Pneumatinis plastikas PT 36, nekaitinamas
DE/CA59/124.98	700096	Atsarginis ekranas PT 36
DE/CA59/124.98	851243	O žiedas plastikiniam P mėgintuvėliui PT 36
DE/CA64/JaegerToe/001	706175	Vožtuvo galvutės atvarto vožtuvas
DE/CA64/JaegerToe/007	892102	Silikoninis kandiklis vaikams
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, vienkartinis, 25 vienetai
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlow™, 12 vienetų
DE/CA64/JaegerToe/007	V-892894	Kandiklis (vienkartinis mėlynas kandiklis), 180 vienetų
DE/CA59/209.2001	720252	Rankinės kalibracijos švirškėtas, 1 L
DE/CA59/209.2001	720254	Rankinės kalibracijos švirškėtas, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm, rankinės kalibracijos švirškėtui, 3 L
DE/CA64/00151871	852352	Alkūnė 45°30 mm inner cone
DE/CA64/00151871	852353	Adapteris ID 30
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putos, 100 vienetų
DE/CA64/00151869	S42101	Vienkartinis nosies spaustukas, 10 vienetų
DE/CA64/00151869	S761889	Vienkartinis nosies spaustukas, 100 vienetų
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard type IIB, 80 vienetų
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard type IIC, 80 vienetų
DE/CA64/00151871	V-861449	Silikoninis adapteris
DE/CA64/00151871	705388	Y adapteris
DE/CA59/124.98	705392	Kontrolinis atsparumas, skirtas IOS
DE/CA59/124.98	705368	Šiluminis atsparumas, skirtas IOS
DE/CA59/065.04	705094	IOS kvėpavimo kaukė vaikams (2-4 metų amžiui)
DE/CA59/050.04	V-892020	APS AirLife® filtras, 50 vienetų
DE/CA64/00151871	V-707307	APS jungties blokas V2 šoniniam srautui
DE/CA59/128.98	V-707288	Purkštuvų rinkinys Sidestream® su 3 papildomais daugkartiniais purkštuvų indais ir suslėgto oro vamzdeliu
DE/CA59/128.98	V-892610	Purkštuvų šoninis srautas, daugkartinis
DE/CA59/128.98	V-892608	Purkštuvų šoninis srautas, vienkartinis, 50 vienetų
DE/CA59/128.98	845579	Purkštuvų galo dangtelis Medic-Aid
DE/CA59/125.98	892137	Nosies adapteris, 1 dydis, 50 vienetų / dėžėje
DE/CA59/125.98	892138	Nosies adapteris, 2 dydis, 50 vienetų / dėžėje
DE/CA59/125.98	892139	Nosies adapteris, 3 dydis, 50 vienetų / dėžėje
Atsarginė dalis / ne medicinos prietaisas	852195	Kištuko nipelis vamzdeliui, ID3/ID2
DE/CA64/JaegerToe/009	852635	Silikoninis vamzdelis, diametras 3x1.5 mm
DE/CA59/065.04	V-982186	CPET kaukė 7450 V2, dydis L, pilna
DE/CA59/065.04	V-982185	CPET kaukė 7450 V2, dydis M, pilna
DE/CA59/065.04	V-982184	CPET kaukė 7450 V2, dydis S, pilna
DE/CA59/065.04	V-982187	CPET kaukė 7450 V2, dydis XS, pilna
DE/CA59/065.04	V-982188	CPET kaukė 7450 V2, dydis smulkus, pilna
DE/CA64/00151871	V-982192	Lankščios kaukės adapteris
DE/CA59/065.04	V-982181	Galvos įranga Oro Nasal kaukei 7450V2, dydis L

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## Atitikties deklaracija

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Vyntus SPIRO, Vyntus PNEUMO, Vyntus IOS, Vyntus APS, Vyntus CPX, Vyntus ECG, Vyntus WALK priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/065.04	V-982180	Galvos įranga Oro Nasal kaukei 7450V2, dydis M
DE/CA59/065.04	V-982189	Galvos įranga Oro Nasal kaukei 7450V2, dydis ES ir smulkus
DE/CA59/065.04	V-982195	Apyrankės rinkinys, dydis L, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982196	Apyrankės rinkinys, dydis M, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982197	Apyrankės rinkinys, dydis S, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982198	Apyrankės rinkinys, dydis XS, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982199	Apyrankės rinkinys, dydis smulkus, skirta CPET kaukei 7450 V2
DE/CA59/125.98	V-982179	Oro Nasal 6450 V2 vienkartinė su HG, dydis L, 18 vienetų / dėžėje
DE/CA59/125.98	V-982178	Oro Nasal 6450 V2 vienkartinė su HG, dydis M, 18 vienetų / dėžėje
DE/CA59/125.98	V-982177	Oro Nasal 6450 V2 vienkartinė su HG, dydis S, 18 vienetų / dėžėje
DE/CA59/125.98	V-982182	Oro Nasal 6450 V2 vienkartinė su HG, dydis ES, 18 vienetų / dėžėje
DE/CA59/125.98	V-982183	Oro Nasal 6450 V2 vienkartinė su HG, dydis smulkus, 18 vienetų / dėžėje
DE/CA59/119.98	V-707326	Tūrio daviklis DVT, pilnas
DE/CA59/119.98	982094	Tūrio daviklio įdėklas
DE/CA64/00151871	V-861078	Adapteris Jaeger kūginis, skirtas DVT Vyntus CPX
DE/CA64/JaegerToe/009	V-707327	Dujų mėginio vamzdelis, dvigubas vamzdelis, 2.40 m
Atsarginė dalis / ne medicinos prietaisas	923015	O2 kuro elementas
DE/CA59/043.04	992582	Ausies spaustuko daviklis, skirtas SpO2
DE/CA59/043.04	992506	SpO2 lankstus daviklis su laidu suaugusiems
DE/CA59/043.04	992578	Suaugusiųjų Flexi Wrap lipni juosta, skirta lanksčiam davikliui (25 vienetų pakuotė)
DE/CA59/043.04	V-992528	SpO2 atspindėjimo kaktos daviklis 8000R
DE/CA59/043.04	V-992529	SpO2 atspindėjimo daviklio laikiklis
DE/CA64/JaegerToe/009	V-707309	Slėgio reduktorius su jungties vamzdeliu mini dujų cilindru
DE/CA64/JaegerToe/010	V-892587	Kalibravimo dujos 5 % CO2, 16 % O2, likusios N2, 0.8L
DE/CA64/JaegerToe/010	V-892551	Dujų cilindras 0.8 L testo dujoms
DE/CA59/1558/2019-R/Lg	992368	Vienkartiniai elektrodai (poilsio), 50 vienetų
DE/CA59/1558/2019-R/Lg	892205	Vienkartiniai elektrodai (streso), 25 vienetai
DE/CA59/130.98	806502	1.5V AA baterija "Varta Industrial"
DE/CA59/130.98	V-806520	NiMH įkraunama baterija 1.2 V AA ≥ 2500 mAh
DE/CA59/2098.1-2015/KE	V-996146	NiMH baterijos įkroviklis
Atsarginė dalis / ne medicinos prietaisas	V-841234	Maišas, skirtas Vyntus EKG, 25 vienetai
DE/CA64/JaegerToe/001	V-861109	HR – vožtuvas 2730, pilnas
DE/CA59/2095.1-2015/KE	852828	Kvėpavimo maišai 20 L (30 / pakuotėje)
DE/CA59/066.04	V-707332	DVT pilnas aukštam / žemam FIO2
DE/CA64/00151871	707146	Hans-Rudolph inhaliatoriaus adapteris
DE/CA64/00151871	706823	Užpildymo montažas maišui
DE/CA59/049.04	V-861721	Galvos fiksacija aukštam / žemam FiO2
DE/CA64/00151871	707065	Jungiamoji žarna
DE/CA59/050.04	V-841191	Vieno paciento gaubto rinkinys, 50 vienetų (50 x MicroGard filtrų + 50 x folijos)
DE/CA64/00151921	V-841182	Gaubto folija, 50 vienetų pakuotė
DE/CA64/JaegerToe/009	V-821555	Canopy vamzdelis
DE/CA64/00151871	706265	Didelis adapteris
DE/CA64/00151871	852351	Kūgio adapteris
DE/CA64/00151921	V-861108	Laikiklis gaubtui
DE/CA64/JaegerToe/001	V-707334	Jet tipo vožtuvas
DE/CA64/00151921	V-835490	Kištukas gaubtui, 2 vienetų pakuotė
DE/CA64/JaegerToe/010	343802 2	Litrinis plieno cilindras su kalibracijos dujomis, su slėgio reduktoriumi (706547) ir jungties vamzdeliu
DE/CA64/JaegerToe/010	892530	Kalibracijos dujos 4.9 % - 6.2 % CO2, 14.5 % - 16 % O2, likusios N2, 2 L
DE/CA64/JaegerToe/010	892553	2 litrų dujų cilindras tyrimo dujoms
Disinfectant of the Shelve	890008	Dezinfektanto tipas "Descogen® I", 1000 g

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## Atitikties deklaracija

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### Vyntus BODY priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA64/JaegerToe/007	892102	Silikoninis kandiklis vaikams
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, vienkartinis, 25 vienetai
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlowTM, 12 vienetai
DE/CA64/JaegerToe/007	V-892894	Kandiklis (vienkartinis mėlynas kandiklis), 180 vienetai
DE/CA59/209.2001	720252	Rankinės kalibracijos švirkštas, 1 L
DE/CA59/209.2001	720254	Rankinės kalibracijos švirkštas, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm rankinės kalibracijos švirkštui, 3 L
DE/CA64/00151871	V-861449	Silikoninis adapteris
DE/CA64/00151871	852353	Adapteris ID 30
DE/CA64/00151869	892120	Plastikinis nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putas, 100 vienetai
DE/CA64/00151869	S42101	Vienkartinis nosies spaustukas, 10 vienetai
DE/CA64/00151869	S761889	Vienkartinis nosies spaustukas, 100 vienetai
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard type IIB, 80 vienetai
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard type IIC, 80 vienetai
DE/CA59/050.04	V-892020	APS AirLife® filtras, 50 vienetai
DE/CA64/00151871	V-707307	APS jungties blokas V2 šoniniam srautui
DE/CA59/128.98	V-707288	Purkštuvų rinkinys Sidestream® su 3 papildomais daugkartiniais purkštuvų indais ir suslėgto oro vamzdeliu
DE/CA59/128.98	V-892610	Purkštuvų šoninis srautas, daugkartinis
DE/CA59/128.98	V-892608	Purkštuvų šoninis srautas, vienkartinis, 50 vienetai
DE/CA59/128.98	845579	Purkštuvų galo dangtelis Medic-Aid
DE/CA59/119.98	V-707377	USS modulis su adapteriu ir apsauginiu dangteliu
DE/CA64/00151871	V-707380	USS MicroGard adapteris
Atsarginė dalis / ne medicinos prietaisas	V-707384	Laidų angos apsauginis dangtis, 5 vienetai
DE/CA59/066.04	V-707389	FPV blokas
DE/CA59/066.04	V-707388	FPV užrakto mechanizmas
DE/CA64/JaegerToe/001	V-707390	FPV silikono vožtuvai, 5 vienetai
DE/CA59/066.04	V-707397	FPV X žiedo rinkinys, sudarytas iš 3 x X žiedų ir 1 x mažo strypo
Disinfectant of the Shelve	V-707382	Automatizuotos dezinfekcijos pakuotė
DE/CA59/119.98	V-707383	USS modulio laikiklis
DE/CA59/066.04	V-707393	FPV bloko laikiklis
Disinfectant of the Shelve	V-707394	Dezinfekavimo padėklo įdėklas
DE/CA64/00151871	V-707381	USS MicroGard adapteris dujų bandiniui paimti
DE/CA64/JaegerToe/009	V-852554	Džiovinimo vamzdelis ME serijai, 48 colių
DE/CA64/JaegerToe/010	892566	Dujų mišinys 0.3 % CO, 0.3 % CH4, 0.3 % C2H2, 21 % O2, likusios N2, 10 litrų
DE/CA64/JaegerToe/010	892542	Dujų cilindras, 10 litrų

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## Atitikties deklaracija

Puslapis 13 iš 16

### BabyCO, MicroCO, Smoke Check priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA64/JaegerToe/007	36-PSA1200	Pediatrinis kandiklis
DE/CA64/00151871	36-PSA2000	Kandiklio adapteris
DE/CA64/00151871	36-PSA1100	Pediatrinis adapteris
DE/CA59/130.98	36-BAT1002	Šarminė PP3 baterija
Atsarginė dalis / ne medicinos prietaisas	36-MEC1184	Kalibravimo įrankis
DE/CA64/JaegerToe/010	36-MCG020	Vienartinės kalibravimo tikrinimo dujos
Atsarginė dalis / ne medicinos prietaisas	36-MGA222	MicroFlow slėgio reduktorius, skirtas Medican kalibravimo dujų kanistrui su srauto indikatoriumi
DE/CA64/00151871	36-MEC1007	22 mm reduktoriaus jungtis kalibracijai
Atsarginė dalis / ne medicinos prietaisas	36-CAB1000	Sąsajos laidas PUMA programinei įrangai
Disinfectant of the Shelve	36-SSC5000A	Perasafe sterilizavimo tirpalas – 81g
DE/CA64/00151869	36-VOL2104	Nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas

### MicroRPM priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/050.04	36-FIL6050	Bakterinis filtras
DE/CA59/050.04	36-FIL6050A	Bakterinis filtras ir adapteris
DE/CA64/JaegerToe/007	36-MTH6410	Gumos flanšinis kandiklis
DE/CA64/JaegerToe/001	36-ASS1221	Iškvėpimo slėgio vožtuvas
DE/CA64/JaegerToe/001	36-ASS1222	Iškvėpimo slėgio vožtuvas
DE/CA59/125.98	36-NPROBE01	Ypač maži nosies zondai
DE/CA59/125.98	36-NPROBE02	Maži nosies zondai
DE/CA59/125.98	36-NPROBE03	Vidutiniai nosies zondai
DE/CA59/125.98	36-NPROBE04	Dideli nosies zondai
DE/CA64/00151871	36-ASS1091	Nosies zondo adapteris
Atsarginė dalis / ne medicinos prietaisas	36-MEC1299	Kalibravimo atsuktuvus
DE/CA59/130.98	36-BAT1002	Šarminė PP3 baterija
Disinfectant of the Shelve	36-SSC5000A	Perasafe sterilizavimo tirpalas – 81g
DE/CA64/JaegerToe/010	36-ASS1234	Slėgio kalibravimo rinkinys
Atsarginė dalis / ne medicinos prietaisas	36-CAB1000	Sąsajos laidas PUMA programinei įrangai

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## Atitikties deklaracija

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**Micro I, MicroDiary, SpiroUSB, MicroLab, MicroLoop, PulmoLife priedai:**

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA64/JaegerToe/007	36-PSA1000	Suaugusiųjų kandiklis
DE/CA64/JaegerToe/007	36-SST1250	Suaugusiųjų vienos krypties kandiklis
DE/CA64/JaegerToe/007	36-SST1000	Suaugusiųjų vienos krypties kandiklis
DE/CA64/JaegerToe/007	36-PSA2200	Universalus kandiklis
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetų
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetų
DE/CA64/00151871	36-MFA1010	MicroGard filtro adapteris
DE/CA64/00151871	36-MFA1050	MicroGard filtro adapteris
DE/CA64/JaegerToe/007	36-PSA1200	Pediatriinis kandiklis
DE/CA64/00151871	36-PSA1100	Pediatriinis adapteris
Disinfectant of the Shelve	36-SSC5000A	Perasafe sterilizavimo tirpalas – 81g
DE/CA64/00151869	36-VOL2104	Nosies spaustukas
DE/CA64/00151869	V-892895	Nosies spaustukas
DE/CA64/00151869	V-892900	Nosies spaustukas
DE/CA64/00151869	892121	Nosies spaustuko padelis
DE/CA59/209.2001	36-SM2125	Kalibravimo siurblys
DE/CA64/00151871	36-MLD1621	Kandiklio adapteris
DE/CA59/130.98	36-BAT1043	Baterijos pakuotė (NiMH AA 2.4V, 1600mAh)
DE/CA59/122.98	36-PSU1017	5V DC 1.2A (GlobTek WR9QA1200USBNR-G2267)
Atsarginė dalis / ne medicinos prietaisas	36-PSU1012	Elektros tinklo adapteris
Atsarginė dalis / ne medicinos prietaisas	36-PSU1013	Elektros tinklo adapteris
DE/CA64/00151871	861427	Kalibravimo švirkšto adapteris
DE/CA64/00151871	36-CON1195	PSU adapterio rinkinys – JK, Europa, JAV, Australija
DE/CA64/00151871	V-861449	Silikoninis adapteris
DE/CA59/126.98	36-SPC1000	Spirometrijos AK programinė įranga
Atsarginė dalis / ne medicinos prietaisas	36-CAB1047	USB ilginamasis laidas
DE/CA59/2098.1-2015/Ke	36-ASS1041	SpiroUSB stalo stovas
DE/CA59/119.98	36-TDX1043	Turbina, pilna
DE/CA59/119.98	36-TDX1048	Turbina, pilna
DE/CA59/119.98	36-TDX1050	Turbina, pilna
Atsarginė dalis / ne medicinos prietaisas	36-CAB1098	USB A laidas
Atsarginė dalis / ne medicinos prietaisas	36-CAB1048	USB jungiamasis laidas
Atsarginė dalis / ne medicinos prietaisas	36-CAB1049	USB jungiamasis laidas į spausdintuvą
Atsarginė dalis / ne medicinos prietaisas	36-PSA1600	Terminio spausdintuvo popierius
DE/CA59/2098.1-2015/Ke	36-ASS1244	MicroLoop atrama
Atsarginė dalis / ne medicinos prietaisas	36-CAS1048	Maišas, skirtas PulmoLife

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## Atitikties deklaracija

Puslapis 15 iš 16

### Vyntus ONE priedai:

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA64/JaegerToe/007	892100	Silikoninis kandiklis SM25 (taikoma dalis, nebegaminamas)
DE/CA64/JaegerToe/007	V-892235	Suaugusiųjų silikoninis kandiklis, pakuotė 5 x 892100 (taikoma dalis)
DE/CA64/JaegerToe/007	892102	Vaikiškas silikoninis kandiklis (taikoma dalis, nebegaminamas)
DE/CA64/JaegerToe/007	V-892230	Vaikiškas silikoninis kandiklis, pakuotė 5 x 892102 (taikoma dalis)
DE/CA64/JaegerToe/007	892103	Plastikinis kandiklis, vienkartinis, 25 vienetai (taikoma dalis)
DE/CA64/JaegerToe/007	S773470	Silikoninis kandiklis FreeFlow™, 12 vienetai (taikoma dalis)
DE/CA64/JaegerToe/007	V-892894	Kandiklis (vienkartinis mėlynas kandiklis), 180 vienetai (taikoma dalis)
DE/CA59/209.2001	720252	Rankinės kalibracijos švirškėtas, 1 L (nebegaminamas)
DE/CA59/209.2001	720254	Rankinės kalibracijos švirškėtas, 3 L
DE/CA64/00151871	852740	Silikoninė mova, 60 mm rankinės kalibracijos švirškėtui, 3 L
DE/CA64/00151871	V-861449	Silikoninis ovalus adapteris, skirtas MicroGard IIB
DE/CA64/00151871	852353	Adapteris ID 30
DE/CA64/00151869	892120	Plastikinis nosies spaustukas (taikoma dalis, nebegaminamas)
DE/CA64/00151869	892121	Nosies spaustuko padelis iš putas, 100 vienetai (taikoma dalis)
DE/CA64/00151869	S42101	Vienkartinis nosies spaustukas, 10 vienetai (taikoma dalis, nebegaminamas)
DE/CA64/00151869	S761889	Vienkartinis nosies spaustukas, 100 vienetai (taikoma dalis, nebegaminamas)
DE/CA64/00151869	V-892895	Nosies spaustukas (daugkartinis), 5 vienetai (taikoma dalis)
DE/CA64/00151869	V-892900	Nosies spaustukas (vienkartinis), 10 vienetai (taikoma dalis)
DE/CA59/050.04	V-892384	MicroGard IIC, 50 vienetai (taikoma dalis)
DE/CA59/050.04 + DE/CA64/JaegerToe/007	V-892381	MicroGard IIB su integruotu kandikliu, 50 vienetai (taikoma dalis)
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892391	Filtro rinkinys MicroGard type IIB, 80 vienetai (turi taikomų dalių)
DE/CA59/050.04 + DE/CA64/JaegerToe/007 + DE/CA64/00151869	V-892392	Filtro rinkinys MicroGard type IIC, 80 vienetai (turi taikomų dalių)
DE/CA59/119.98	V-707377	USS modulis su adapteriu ir apsauginiu dangčiu
DE/CA64/00151871	V-707380	USS MicroGard adapteris
DE/CA64/00151871	V-707381	USS MicroGard adapteris dujų mėginiui paimti
DE/CA64/JaegerToe/009	V-707722	Mėginio linija Vyntus ONE
Atsarginė dalis / ne medicinos prietaisas	V-707384	Laidų angos apsauginis dangtis, 5 vienetai
DE/CA64/JaegerToe/001	V-707721	FPV blokas eDemand su 2 x silikoniniais vožtuvais
DE/CA59/066.04	V-707744	FPV užrakto mechanizmas, c formos
DE/CA64/JaegerToe/001	V-707390	FPV silikoniniai vožtuvai, 5 vienetai
DE/CA59/066.04	V-707741	Korpusinis spaustukas FPV eDemand
DE/CA59/119.98	V-707383	USS modulio laikiklis
Disinfectant of the Shelve	V-707394	Dezinfekavimo padėklo įdėklas
DE/CA64/JaegerToe/010	892566	Dujų mišinys 0.3 % CO, 0.3 % CH4, 0.3 % C2H2, 21 % O2, likusios N2, 10
DE/CA64/JaegerToe/010		Litrų (dujos difuzijos matavimui)
DE/CA64/JaegerToe/010	892566R	Medicininį dujų mišinys 0.3 % CO, 0.3 % CH4, 0.3 % C2H2, 21 % O2, likusios N2, 10 litrų (dujos difuzijos matavimui – tik Vokietijai)
DE/CA64/JaegerToe/010	892542	Dujų cilindras, 10 litrų (dujoms 892533, 892566, 892566R, 892546)
DE/CA64/JaegerToe/010	892501	Medikamentinis produktas O2 medicininiam tikslams, 10 litrų
DE/CA64/JaegerToe/010	892543	Dujų cilindras, 10 litrų medikamentiniam produktui O2 (dujoms 892501)
DE/CA64/JaegerToe/010	V-892592	Vyntus ONE kalibravimo dujos 16 % O2, 5 % CO2, 0.3 % CH4, 0.3 % CO, 0.3 % C2H2, likusios N2, 80 litrų
DE/CA64/JaegerToe/010	V-892495	Dujų cilindras 0.5 litrų kalibravimo dujoms (dujoms V-892592)
DE/CA59/125.98	892137	Nosies adapteris, 1 dydis, 50 vienetai / dėžėje (taikoma dalis)
DE/CA59/125.98	892138	Nosies adapteris, 2 dydis, 50 vienetai / dėžėje (taikoma dalis)
DE/CA59/125.98	892139	Nosies adapteris, 3 dydis, 50 vienetai / dėžėje (taikoma dalis)
DE/CA59/065.04	852715	Veido kaukė rinomanometrijai (Rhino) (taikoma dalis)
DE/CA64/00151871	V-707723	Kūginis adapteris su anga (Rhino)
DE/CA64/00151871	V-708052	Jungties rinkinys (sudarytas iš 852367, V-852039, 852635, ir 852633)
DE/CA59/207.2001	705003	Esophagus Catheter rinkinys, 5 vienetai (taikoma dalis)
DE/CA59/119.98	V-707326	Tūrio daviklis DVT (skaitmeninis tūrio daviklis), pilnas
DE/CA59/119.98	982094	Tūrio daviklio įdėklas

Produkto nr.: V-785032 Perž. 4

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Vyaire Medical GmbH | Leibnizstrasse 7 | 97204 Hoechberg | Tel. +49 931 4972-0 | Produkto nr. 791021

## Atitikties deklaracija

Puslapis 16 iš 16

DIMDI registracijos numeris	Produkto numeris	Apibūdinimas
DE/CA59/119.98	V-707725	Tūrio daviklio įdėklas, vienkartinis
DE/CA64/00151871	V-861078	Adapteris Jaeger cone, skirtas DVT Vyntus
Atsarginė dalis / ne medicinos prietaisas	923015	O2 kuro elementas
DE/CA59/043.04	992582	Ausies spaustuko daviklis, skirtas SpO2 (Nonin Model 8000Q2) (taikoma dalis)
Atsarginė dalis / ne medicinos prietaisas	V-841188	Kalibracijos dujų laikiklis (0.8/0.38 L)
DE/CA64/JaegerToe/010	706183	Dujų butelio sienos montažas
DE/CA59/043.04	992506	SpO2 lankstus daviklis su laidu suaugusiems (Nonin Model 8000J-3) (taikoma dalis)
DE/CA59/043.04	992578	Suaugusiųjų Flexi Wrap lipni juosta, skirta lanksčiam davikliui (25 vienetų pakuotė)
DE/CA59/043.04		(Nonin Model 8000JFW) (taikoma dalis)
DE/CA59/043.04	V-992528	SpO2 Reflectance Forehead Sensor (Nonin Model 8000R) (taikoma dalis)
DE/CA59/043.04	V-992529	SpO2 atspindėjimo daviklio laikiklis (Nonin Model 8000H) (taikoma dalis)
DE/CA59/043.04	V-992512	Nonin XPOD 3011 LP w. ODU
DE/CA59/065.04	V-982186	CPET kaukė 7450 V2, dydis L, pilna (taikoma dalis)
DE/CA59/065.04	V-982185	CPET kaukė 7450 V2, dydis M, pilna (taikoma dalis)
DE/CA59/065.04	V-982184	CPET kaukė 7450 V2, dydis S, pilna (taikoma dalis)
DE/CA59/065.04	V-982187	CPET kaukė 7450 V2, dydis XS, pilna (taikoma dalis)
DE/CA59/065.04	V-982188	CPET kaukė 7450 V2, dydis smulkus, pilna (taikoma dalis)
DE/CA64/00151871	V-982192	Lanksčios kaukės adapteris
DE/CA59/065.04	V-982181	Galvos įranga Oro Nasal kaukei 7450V2, dydis L (taikoma dalis)
DE/CA59/065.04	V-982180	Galvos įranga Oro Nasal kaukei 7450V2, dydis M (taikoma dalis)
DE/CA59/065.04	V-982189	Galvos įranga Oro Nasal kaukei 7450V2, dydis ES ir smulkus (taikoma dalis)
DE/CA59/065.04	V-982195	Apyrankės rinkinys, dydis L, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982196	Apyrankės rinkinys, dydis M, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982197	Apyrankės rinkinys, dydis S, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982198	Apyrankės rinkinys, dydis XS, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982199	Apyrankės rinkinys, dydis smulkus, skirta CPET kaukei 7450 V2
DE/CA59/065.04	V-982179	Oro Nasal 6450 V2 vienkartinė su HG, dydis L, 18 vienetų / dėžėje (vienkartinė kaukė) (taikoma dalis)
DE/CA59/065.04	V-982178	Oro Nasal 6450 V2 vienkartinė su HG, dydis M, 18 vienetų / dėžėje (vienkartinė kaukė) (taikoma dalis)
DE/CA59/065.04	V-982177	Oro Nasal 6450 V2 vienkartinė su HG, dydis S, 18 vienetų / dėžėje (vienkartinė kaukė) (taikoma dalis)
DE/CA59/065.04	V-982182	Oro Nasal 6450 V2 vienkartinė su HG, dydis ES, 18 vienetų / dėžėje (vienkartinė kaukė) (taikoma dalis)
DE/CA59/065.04	V-982183	Oro Nasal 6450 V2 vienkartinė su HG, dydis smulkus, 18 vienetų / dėžėje (vienkartinė kaukė) (taikoma dalis)
DE/CA59/1558/2019-R/Lg	992368	Vienkartiniai elektrodai (poilsio), 50 vienetų (taikoma dalis)
DE/CA59/1558/2019-R/Lg	892205	Vienkartiniai elektrodai (streso), 25 vienetai (taikoma dalis)
DE/CA59/130.98	806502	1.5V AA baterija "Varta Industrial"
DE/CA59/130.98	V-806520	NiMH įkraunama baterija 1.2 V AA ≥ 2500 mAh
DE/CA59/2098.1-2015/KE	V-996146	NiMH baterijos įkroviklis
Atsarginė dalis / ne medicinos prietaisas	V-841234	Maišas, skirtas Vyntus EKG, 25 vienetai (taikoma dalis)

Produkto nr.: V-785032 Perž. 4

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The following parts are suitable for these products:

MasterScreen Pneumo | MasterScreen IOS | MasterScreen Diffusion  
 MasterScreen Body/Diffusion | MasterScreen PFT | MasterScope Body  
 Vyntus™ SPIRO | Vyntus™ PNEUMO | Vyntus™ IOS | Vyntus™ APS | Vyntus™ BODY | Vyntus™ ONE

**MicroGard™ II Bacterial/Viral Filter**

<b>MicroGard IIB single use bacteria filter with integrated mouthpiece</b>		For Device	
		All PFT devices (except APS)	
Package	50 pieces	<div style="border: 2px solid red; padding: 5px; display: inline-block;"> <b>47.1.1. MicroGard filtras vienkartinio naudojimo</b> </div>	
Package	V-892381		
<b>Filter Kit MicroGard Type IIB single use</b>		For Device	
		All PFT devices (except APS)	
Package	80 pieces		
Package	V-892391		
<b>MicroGard IIC single use bacteria filter</b>		For Device	
		All PFT devices (except APS)	
Package	50 pieces	Can be used in combination with mouthpieces. Connection to mouthpiece outer diameter 30 mm.	
Package	V-892384		

<b>Filter Kit MicroGard Type IIC single use</b>		For Device	
		All PFT devices (except APS)	
Package	80 pieces		
Package	V-892392		



MicroGard® II  
pulmonary function filter

# MicroGard® II pulmonary function filter

Our filters provide an easy way to help ensure protection from cross-contamination. The MicroGard II stands for patient and operator safety without compromising on system performance and clinical output.

## Key Features

47.1.1. Antivirusinis ir antibakterinis

- 99.999% viral and bacterial efficiency against cross contamination (based on Nelson Test Report 10003754)
- Low resistance to airflow
- Minimal dead space (55 mL)
- Filter housing and filter fleece tested for biocompatibility
- Three filter configuration versions, two package sizes
- Validated for compliance with the complete Vyaire Respiratory Diagnostics product line



MicroGard IIB integrated oval-shaped mouthpiece

47.1.1. MicroGard IIB filtras su integruotu kandikliu



MicroGard II filters are the filters of choice for use with Vyntus™, Vmax®, MasterScreen, and Micro Medical pulmonary function testing (PFT) instrumentation.

## The MicroGard II filter series

- **MicroGard IIB** with integrated oval shaped mouthpiece suitable for adult and pediatric use\*
- **MicroGard IIC** with round shaped connector for use with special lung function mouthpieces, ideal for gas dilution and body plethysmographic measurements

Nelson Laboratory has done extensive testing on the MicroGard II filter.<sup>1</sup> This testing shows that the filter offers the right balance between optimized filtration efficiency and minimal resistance (*Delta P*) to airflow. Based on strict Vyair verification and validation processes, the MicroGard II does not affect equipment measurement characteristics while protecting patient, operator and equipment from cross-contamination.

### Product specifications

- Inspiratory resistance: < 0.04 kPa/LPS at 1 L/sec (< 0.4 cmH<sub>2</sub>O/L/sec at 1 L/sec)
- Expiratory resistance: < 0.04 kPa/LPS at 1 L/sec (< 0.4 cmH<sub>2</sub>O/L/sec at 1 L/sec)
- Filtration efficiency against cross contamination:
  - Bacterial > 99.999%  
(based on Nelson Test Report 10003754)
  - Viral > 99.999%  
(based on Nelson Test Report 10003754)

47.1.6. Įkvėpimo pasipriešinimas < 0,4 cm H<sub>2</sub>O/l/s, esant 1 l/s oro srautui

47.1.7. Iškvėpimo pasipriešinimas < 0,4 cm H<sub>2</sub>O/l/s, esant 1 l/s oro srautui

47.1.5. Filtravimo efektyvumas (bakterijų, virusų sulaikymas) 99,999%.



Ordering information			
2384	MicroGard IIC (single filter, round connector)		50
V-892391	Filter kit (MicroGard IIB, nose clip)		80
V-892392	Filter kit (MicroGard IIC, disposable mouthpiece, nose clip)		80

\* Minimum body weight of 27.5 kg



## REFERENCES

1. A. Sandall, "Virus Filtration Efficiency Test (VFE) at an Increased Challenge Level GLP Report", Nelson Laboratories, UT, Salt Lake City, Laboratory Number 530460, May 2010

## GLOBAL HEADQUARTERS

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# CardioPulmonary Review

## MicroGard™ II

Next generation  
Pulmonary Filter  
with validated filter  
and equipment  
performance



47.1.4. Vienas galas  
apvalus, kitas ovalus

MicroGard™ IIB



MicroGard™ IIC

The use of pulmonary filters is becoming more and more a mandatory requirement in Respiratory Care departments throughout the world to be able to comply with the more stringent hygiene standards in hospitals. Hospital acquired infections are one of the reasons why the cost of healthcare is increasing and in the Respiratory Care field the use of validated pulmonary filters is an efficient measure to prevent contamination. Pulmonary filters do not only prevent contamination of the equipment by potential pathogen transmission via the patient's exhaled air but also prevent patient cross contamination. Furthermore it protects the staff from coming in direct contact with the exhaled air during the breathing manoeuvres.

47.1.1. MicroGard  
filtras naudojamas  
plaučių funkcijų  
tyrimams.

CareFusion has been manufacturing this type of filter for over a decade. The MicroGard™ II filter is used in combination with pulmonary instrumentation from CareFusion's strong brands JAEGER, SensorMedics® and Micro Medical. The growing demand for cost control and increased hygiene guidelines for medical devices were key drivers for the development of the new MicroGard™ II filter.

[www.carefusion.co.uk/microgard](http://www.carefusion.co.uk/microgard)



## Introduction

The use of pulmonary filters on lung function equipment has an impact on the characteristics of the equipment. Filter dead space, resistance and filter material properties all play an important role in this. Filter properties depend on the right balance between thickness and area of the filter material. This determines the resistance the patient is experiencing, when exhaling and inhaling through the filter. A viral or bacterial efficacy of 99.999% can be obtained but most likely the resistance will be unacceptably high. The MicroGard™ II has been designed to optimise this trade off and is the only filter that has gone through a full verification and validation process together with the Medical Equipment it is used on hence we can guarantee optimum measurement performance of the CareFusion's JAEGER, SensorMedics® Vmax and Micro Medical Pulmonary Instrumentation. As stated, filters do influence the equipment's characteristics and where applicable our linearization tables for the flow sensors are corrected to generate the most accurate measurement results when the MicroGard™ II filter is used. This level of accuracy cannot be guaranteed when other, none validated, filters are used in combination with CareFusion equipment.



MicroGard™ IIB Pulmonary Laboratory Setting with Filter by MasterScreen

A new manufacturing facility has been created to ensure an optimum manufacturing environment for the filter production. When you order the CareFusion MicroGard™ II filter, you get a product that has been produced using the highest quality materials, stringent manufacturing standards, and extensive quality control measures. Quality systems in CareFusion Respiratory Systems division at our manufacturing facilities are certified to meet DIN EN ISO 9001 and DIN EN ISO 13485 standards. The MicroGard™ II filter material has been tested for Biocompatibility<sup>1</sup>.



MicroGard™ IIB Pulmonary Laboratory Setting with Filter by Vmax

## Independent Testing<sup>ii</sup>

A recently performed series of scientific tests of the MicroGard™ II filters was carried out at Nelson<sup>ii</sup> Laboratories, Salt Lake City, Utah, USA.



Nelson Laboratories performed hundreds of bacterial removal efficiency tests every week using standardised operating procedures (SOP). The use of SOP's are for both the manufacturer and the customer a proof of reliable independent testing to verify the filter's performance. The Standard Operating Procedure used comprises the following key elements:

- A constant flow of aerosol at a rate of 30 litres per minute
- A mean particle size must be maintained at 3.0 +/- 0.3 µm in accordance with ASTM F2101<sup>iii</sup>
- Testing several filter samples to ensure the efficiency is consistent between different filters.

## Filter Material

The proprietary filter material used in the MicroGard™ II is a special blend of polymers with a highly stable electrostatic charge due to its unique composition. The filter material consistently achieves high efficiencies by deploying both the electrostatic charge as well as mechanical mechanisms to remove airborne particles. The high efficiency of the charged material allows for a more open matrix of fibres, this results in a minimal restriction to the airflow. Most filtration materials use surface loading as the primary means of removal. With the material used in the MicroGard™ II product, the fibre matrix results in depth loading, where particles are captured throughout the entire filter material, not just on the surface. The filter material is composed of polymer fibres that will not support the growth of mould mildew, fungus or bacteria. This

**47.1.3. Filtras pagamintas iš polimerinių pluoštų, atsparių pelėsių, grybelių ar bakterijų kaupimuisi**

## Bacterial/Viral Efficiency

It is important to know that the viral filtration efficiency was performed using the bacteriophage virus which, at 0.027 microns, is one of the smallest known viruses. It is considered to represent a severe challenge to the filter material due to its diminutive size and morphology. In comparison, the HIV virus is 0.042 microns while the Hepatitis C is 0.03 microns. Bacteria such as Tuberculosis, by contrast, are much larger in size than viruses.

The MicroGard™ II comes in 4 filter variations:

1. The MicroGard™ IIB with integrated oval mouthpiece; the unique positioning support (design patent DE202010009616U1) on the integrated oval mouthpiece is assisting the patient with the correct positioning of the teeth/lips to avoid air leakage around the lips.
2. Filter kit IIB with MicroGard™ IIB with integrated mouthpiece ideal packed with single use noseclip.
3. The MicroGard™ IIC with round connector for use in combination with a separate mouthpiece.
4. Filter kit IIC with MicroGard™ IIC with round shaped connector plus disposable mouthpiece and noseclip. Ideal for gas dilution and bodyplethysmographic measurements.



Filter kit MicroGard™ IIC with disposable rubber mouthpiece and noseclip. Ideal for gas dilution testing and for poorly cooperating subjects.

The filter performance specifications are identical.

## Flow Rate

It is crucial for the clinician to be aware that the bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) are correlated to the basis weight of the filter media, which is also correlated to the flow resistance, referred as the Delta P ( $\Delta P$ ). As the base weight increases, the filtration efficiencies are higher and so is the Delta P. The scientific challenge therefore is to obtain the best possible BFE and VFE efficiency without jeopardising a higher Delta P.

- NAMSA has performed the following tests:
  - ISO Intracutaneous Study - Extract
  - Murine Local Lymph Nody Assay (LLNA) -(SC and DMSO Extracts)
  - Cytotoxicity Study Using the ISO Elution Method (1X MEM Extract)
- Nelson Report 10003754 - Viral Filtration Efficiency Test (VFE) at an Increased Challenge level GLP Report  
Nelson Report 10003754 - Bacterial Filtration Efficiency Test (BFE) at an Increased Challenge level GLP Report
- ASTM F2101
- HENDERSON, D. W. (1952): An apparatus for the study of airborne infections. J. Hyg. Camb. 50, 53-67  
DRUETT, H. A. (1969). A mobile form of the Henderson apparatus. J. Hyg. Camb. 67, 437-448.

Measurement Quality with optimum performance balance

- Inspiratory Resistance: <0.04 kPa/(L/s) at 1 L/s (<0.4 cmH<sub>2</sub>O/(L/s) at 1 L/s)
- Expiratory Resistance: <0.04 kPa/(L/s) at 1 L/s (<0.4 cmH<sub>2</sub>O/(L/s) at 1 L/s)
- Filter Efficiency against cross contamination: Bacterial > 99.999% (based on Nelson Lab test)<sup>ii</sup>  
Viral > 99.999% (based on Nelson Lab test)<sup>ii</sup>
- Filter effective dead space volume: 55 mL

## Conclusion

Based upon the scientific test results conducted by Nelson Laboratories, the MicroGard™ II Filter proves to have the combination of greatest filtration efficiency with lowest resistance (Delta P) to airflow. Based on CareFusion's validation and verification processes MicroGard™ II does not compromise equipment measurement characteristics. We recommend using only MicroGard™ II filters in combination with CareFusion JAEGER MasterScreen/Vyntus, SensorMedics® Vmax and Micro Medical pulmonary instrumentation.

## Ordering information

- V-892381 MicroGard™ IIB - Box of 50
- V-892391 Filter kit (MicroGard™ IIB + noseclip) - Box of 80
- V-892384 MicroGard™ IIC - Box of 50
- V-892392 Filter kit (MicroGard™ IIC + disposable rubber mouthpiece + noseclip) - Box of 80
- V-861449 Silicon adapter oval for volume calibration MicroGard™ IIB
- 852740 Silicon sleeve (60 mm) for volume calibration MicroGard™ IIC
- MFA1010 Adapters MicroGard™ to MicroMedical, pack of 10
- MFA1050 Adapters MicroGard™ to MicroMedical, pack of 50

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V-791711  
Version 05.00

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