

	EC Declaration of Conformity <i>EG Konformitätserklärung</i>	Date / Datum 2015-11-19
	European Directive 93/42/EEC, Annex VII European Directive 2011/65/EC <i>Europäische Richtlinie 93/42/EWG, Anhang VII</i> <i>Europäische Richtlinie 2011/65/EG</i>	Document ID / Dokument Nr. MD108-014-1511-125-0

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

hereby declares that the / *erklärt hiermit, dass*

Product name	Medical device /	Device Class	UMDNS Code / GMDN Code
Mounting System	Mounts, Monitor	I	15-311
Hinged Arms	Positioning Aids	I	16-223 / 37040
Clamp Modification Kit, Lever-Type Clamp, Rail Clamp, Rail holder w. Clamp, Clamp, Multimed Pod Mount	Carriers Medical Device	I	11-835 / 41893
Aspiration Hose Holder, Connecting Hose Holder	Carriers Medical Device	I	11-835 / 37075
Rail Support	Carriers Medical Device	I	11-835 / 35954
Basket	Hamper	I	15-839 / 35954
Dish	Bowls	I	15-561 / 42893

meets the provisions of the following European Directives:

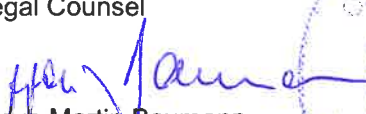
- 93/42/EEC on medical devices. The procedure according to Annex VII of the above mentioned directive has been followed.
 - 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment. This declaration is effective for products placed on the market as of the date of issue.
- Any modifications of the medical device not authorized by Draeger Medical will invalidate this declaration.

mit den Bestimmungen der folgenden europäischen Richtlinien übereinstimmt:

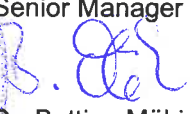
- 93/42/EEG über Medizinprodukte. Das Verfahren gemäß den Vorgaben in Anhang VII derselben Richtlinie wurde eingehalten.
- 2011/65/EG zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten.

Diese Erklärung ist gültig für ab dem Ausstellungsdatum in Verkehr gebrachte Produkte. Jede nicht durch Draeger Medical autorisierte Modifikation an dem Medizinprodukt führt zur Ungültigkeit dieser Erklärung.

Legal Counsel


Claus Martin Baumann

Senior Manager Regulatory Affairs


Dr. Bettina Möbius

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Anton Schrofner

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Extent of conformity assessment / Umfang der Konformitätsbewertung			
Part No. / Sach Nr.	Product name / Produktbezeichnung	Part No. / Sach Nr.	Product name / Produktbezeichnung
2M85705	Quickstop Hinged Arm 1	MP00696	Screw Handle
2M85706	Quickstop Hinged Arm 2	MP00697	Retaining Plate
2M86463	Quickstop Hinged Short	2M85049	Clamp Modification Kit
2M86464	Quickstop Hinged Pod	M25739	Lever-Type Clamp
8409609	Hinged Arm 240°	M20650	Rail Clamp
MP00690	Infinity ACS Hinged Arm	M26842	Rail holder w. Clamp
MP00493	Hose Clip, Coaxial	2M85274	Clamp
MP00583	Hinged Arm, Middle Part	2M86185	Rail Support 40 cm
MP00653	Quickstop Set Multi Med Pod	2M85239	Aspiration Hose Holder
8406138	Set of Hose Clips (2 pc. of 8404761)	2M85446	Connecting Hose Holder
8409746	Support for Y-Piece	M26146	Basket 150
8409841	Hose Clips	M26145	Basket 300
2M86465	Universal Tube Holder Plate	M25121	Basket 600
MP00692	Universal Hose Clip, Box 2	2M85233	Dish
MP00693	Double Hose Clip, Gray	MP00721	Multimed Pod Mount
MP00694	Cover, Box 6	M26391	Spacer
G97650	Mounting System (M26)	G25764	Dbl.arm-frontrail-VESA,300/300
G25700	Infusion arm-38 mm pole, 200	G25765	Dbl.arm-frontrail-VESA, 400/200
G25701	Infusion arm-38mm pole,300	G25766	Dbl.arm-frontrail-VESA, 400/300
G25702	Infusion arm-38mm pole,400	G25767	Dbl.arm-frontrail-VESA, 400/400
G25703	Infusion arm-38mm pole,200/200	G25768	Liftarm15-frontrail-VESA
G25704	Infusion arm-38mm pole,300/200	G25769	Liftarm15-frontrail-VESA,+300
G25705	Infusion arm-38mm pole,300/300	G25770	Liftarm15-frontrail-VESA+keyb
G25706	Infusion arm-38 mm pole, 400/200	G25771	Liftarm15-frontr.-VESA+kb+300
G25707	Infusion arm-38 mm pole, 400/300	G25772	Monitor mount-vert.rail-VESA
G25708	Infusion arm-38mm pole,400/400	G25773	Swivel arm-vert.rail-VESA,200
G25709	Swivel arm-38 mm pole-SLIDE, 200	G25774	Swivel arm-vert.rail-VESA,300
G25710	Swivel arm-38 mm pole-SLIDE, 300	G25775	Swivel arm-vert.rail-VESA,400
G25711	Swivel arm-38 mm pole-SLIDE, 400	G25776	Dbl.arm-vert.rail-VESA,300/300
G25712	Dbl.arm-38 mm pole-SLIDE, 200/200	G25777	Liftarm15-vert.rail-VESA
G25713	Dbl.arm-38 mm pole-SLIDE, 300/200	G25778	Liftarm15-vert.rail-VESA+keyb

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Extent of conformity assessment / Umfang der Konformitätsbewertung			
Part No. / Sach Nr.	Product name / Produktbezeichnung	Part No. / Sach Nr.	Product name / Produktbezeichnung
G25714	Dbl.arm-38 mm pole-SLIDE, 300/300	G25779	Swivel arm-vert.rail-slide,200
G25715	Dbl.arm-38 mm pole-SLIDE, 400/200	G25780	Swivel arm-vert.rail-slide,300
G25716	Dbl.arm-38 mm pole-SLIDE, 400/300	G25781	Swivel arm-vert.rail-slide,400
G25717	Dbl.arm-38 mm pole-SLIDE, 400/400	G25782	Dbl.arm-vert.rail-side,400/200
G25718	Liftarm15-38mm pole-slide	G25783	Liftarm15-vert.rail-slide
G25719	Liftarm15-38mm pole-slide,+300	G25784	Liftarm15-vert.rail-slide+keyb
G25720	Liftarm 15-38 mm pole-slide+KB	G25785	Infusion arm-vert.rail,400/400
G25721	Liftarm 15-38 mm pole-slide+KB, +300	G25786	Swivel arm-EasyLift-VESA,300
G25722	Monitor Mount-38mm pole-VESA	G25787	Dbl.arm-EasyLift-VESA,300/300
G25723	Swivel arm-38 mm pole-VESA, 200	G25788	Swivel arm-hor.rail-VESA,200
G25724	Swivel arm-38 mm pole-VESA, 300	G25789	Swivel arm-hor.rail-VESA,400
G25725	Swivel arm-38 mm pole-VESA, 400	G25790	Dbl.arm-hor.rail-VESA,300/300
G25726	Dbl.arm-38 mm pole-VESA, 200/200	G25791	Swivel arm-hor.rail-slide,200
G25727	Dbl.arm-38 mm pole-VESA, 300/200	G25792	Swivel arm-hor.rail-slide,400
G25728	Dbl.arm-38mm pole- VESA,300/300	G25793	Dbl.arm-hor.rail-slide,300/300
G25729	Dbl.arm-38 mm pole-VESA, 400/200	G25794	Dbl.arm-Westbr.-VESA, 300/300
G25730	Dbl.arm-38 mm pole-VESA, 400/300	G25795	Liftarm15-Westbr.-VESA+keyb.
G25731	Dbl.arm-38 mm pole-VESA, 400/400	G25796	Monitor mount-Westbr.-VESA
G25732	Liftarm15-38mm pole-VESA	G25797	Swivel arm-Westbr.-slide,200
G25733	Liftarm15-38mm pole-VESA,+300	G25798	Swivel arm-Westbr.-slide,300
G25734	Liftarm15-38mm pole-VESA+keyb	G25799	Swivel arm-Westbr.-slide,400
G25735	Liftarm 15-38 mm pole- VESA+KB,+300	G27410	Dbl.arm-v.rail-VESA,300/200L
G25736	Infusion arm-frontrail, 200	G27411	Swiv.arm-vert.rail-VESA,300L
G25737	Infusion arm-frontrail,300	G27412	Infus. arm-vert.rail,300/200L
G25738	Infusion arm-frontrail, 400	G27413	Swiv.arm-vert.rail-Slide,300R
G25739	Infusion arm-frontrail, 200/200	G27414	Liftarm-vert.rail-VESA A500L
G25740	Infusion arm-frontrail,300/200	G27417	Swiv.arm-vert.rail-dblVESA200L
G25741	Infusion arm-frontrail,300/300	G27418	Swiv.arm-vert.rail-VESA,300R
G25742	Infusion arm-frontrail, 400/200	G27419	Swiv.arm-vert.rail-dblVESA200R
G25743	Infusion arm-frontrail, 400/300	G27420	Liftarm-vert.rail-VESA,+Keyb L

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Extent of conformity assessment / Umfang der Konformitätsbewertung			
Part No. / Sach Nr.	Product name / Produktbezeichnung	Part No. / Sach Nr.	Product name / Produktbezeichnung
G25744	Infusion arm-frontrail,400/400	G27421	Liftarm short-v.rail-VESA+Keyb
G25745	Swivel arm-frontrail-slide,200	G27422	Liftarm short-vert.rail-VESA
G25746	Swivel arm-frontrail-slide, 300	G29075	Infus. arm-vert.rail,400/400 (15kg)
G25747	Swivel arm-frontrail-slide,400	G27469	Infus. arm-vert.rail,400/400
G25748	Dbl.arm-frontrail-SLIDE, 200/200	G27517	Swiv.arm GCX-VESA,300 45/45
G25749	Dbl.arm-frontrail-SLIDE, 300/200	G29004	Dbl.arm-vert.rail-VESA,200/200
G25750	Dbl.arm-frontrail-SLIDE, 300/300	G29006	Swfl arm-vert.rail-VESA,200
G25751	Dbl.arm-frontrail-SLIDE, 400/200	G28740	Dpl.Arm-VertSch-VESA,300/200L
G25752	Dbl.arm-frontrail-SLIDE, 400/300	G27423	Infuson arm light-Tslot, 300
G25753	Dbl.arm-frontrail-SLIDE, 400/400	G27424	Swivel arm-Tslot-VESA, 300
G25754	Liftarm 15-frontrail-slide	G27425	Dbl.arm-38mmTube-SLIDE 2x
G25755	Liftarm 15-frontrail-slide,+300	G27426	Sviv.arm-Tslot-VESA,300 50/30
G25756	Liftarm 15-frontrail-slide+KB	G27427	Swiv.arm-Tslot-VESA,400 50/30
G25757	Liftarm 15-frontrail-slide+KB, +300	G27428	Dbl.arm-Tslot-VESA,300/300
G25758	Monitor Mount-frontrail-VESA	G27429	Liftarm-Tslot-VESA, +keyb
G25759	Swivel arm-frontrail-VESA, 200	G27430	Liftarm-Tslot-VESA 50/40
G25760	Swivel arm-frontrail-VESA, 300	G27431	Liftarm-Tslot-VESA 50/30
G25761	Swivel arm-frontrail-VESA,400	G27432	Swivel arm-Tslot-SLIDE,300
G25762	Dbl.arm-frontrail-VESA, 200/200	G27433	Swivel arm-Tslot-SLIDE,400
G25763	Dbl.arm-frontrail-VESA, 300/200	G29313	Lifta.sh.-Tslot-VESA30/30+keyb
G96811	100 mm VESA adapter	G29314	Liftarm sh.-v.rail-VESA30/30
G24531	Keyboard shelf M26	G29315	Lifta.sh.-v.rail-VESA30/30+key
G98838	Accessory pole	G29316	Swiv.arm-v.rail-VESA,300,30/0
G24956	Bracket slide compl.	G29317	Swiv.arm-v.rail-VESA,400,30/0
G24627	Horizontal rail 300mm VESA	G25885	Inf.arm-vert.rail,300 60/60
G24347	Adapter SLIDE- Philips/VESA75/100	G28649	Swiv.arm-v.rail-VESA,300 30/30
G28729	Bracket long	G36326	Dbl.arm-Tslot-Tray, 300/300
G36870	Liftarm 15-38mm pole-slide,s.h.	G36327	Dbl.arm-Tslot-VESA, 200/200
G36871	Liftarm 15-38pol-slide+300,s.h.	G36413	Inf.Arm-Vert-rail,400/200 20kg
G36872	Liftarm 15-frontrail-slide,s.h.	G36414	Dbl-Arm.Vert-VESA 300/200 15kg
G36873	Liftarm 15-front-slide+300,s.h.	G36667	Dbl.Arm-VS-VESA 200/200 rechts
G36874	Liftarm 15-vert.rail-slide,s.h.	G36695	Dbl.arm-38mmTube-SLIDE,200/200
G36875	Liftarm 15-v.rail-slide+300,s.h.	G36908	Dbl-Arm.VertSch-VESA200/300L

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Product name / Produktbezeichnung	Medical device / Medizinprodukt
As stated in EC Declaration of conformity: MD108-014-1511-125-0	
Applied Standards in full or in part / <i>Vollständig oder teilweise angewendete Normen:</i>	
EN 60601-1:2006 +AC 2010 + AMD 11 2011 <i>(IEC 60601-1 :2005+ COR 1 2006 + COR 2 2007)</i>	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6:2010 <i>(IEC 60601-1-6 :2010)</i>	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard - Usability
EN ISO 14971: 2012 <i>(ISO 14971 :2007)</i>	Medical devices - Application of risk management to medical devices
EN ISO 19054 :2006	Rail system for Supporting Medical Equipment
EN ISO 17664: 2004	Sterilization of Medical Devices – Information to be provided by the manufacturer for the reprocessing of resterilizable Medical Devices
EN 980 :2008	Graphical symbols for use in the labelling of medical devices
EN 1041:2008+A1:2013	Information supplied by the manufacturer with medical devices

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