

We, **RENOL SA**, Quai F. Demets 23, 1070 Brussels, Belgium  
declare under our sole responsibility that the CE marked products to which this declaration  
refers are identified as follows:

**Renol Restraint system (for chair):**

RFC29200	RFC29200M	RFC29200RL	RFP22000	RFB10300RL	RFC25100	RFC25200	RFC35095
RFC29400	RFC29400M	RFC29400RL	RFB10200	RFC47400	RFC26000	RFC25300	RFC35115
RFC47115	RFC47115M	RFC47115RL	RFB10200M	RFK01111	RFC26200	RFC51000	RFC35135
RFC47140	RFC47140M	RFC47140RL	RFB10200RL	RFK01222	RFC26300	RFC52000	RFP11000
RFC57115	RFC57115M	RFC57115RL	RFB10300	RFK00100	RFC26400	RFS19050	RFW16025
RFC57140	RFC57140M	RFC57140RL	RFB10300M	RFK00300	RFC45115	RFS20050	
				RFK00400	RFC45135		
				RFK00433			

**Renol Restraint system (for bed):**

RFB08115	RFB08115M	RFB08115RL	RFP22000	RFY21000RL	RFA17550	RFW16210M	RFB11650	RFA17000
RFB08140	RFB08140M	RFB08140RL	RFE24000	RFY21500RL	RFA17550M	RFW16210RL	RFB11650M	RFA17087
RFB09115	RFB09115M	RFB09115RL	RFE24500	RFE24900	RFA17550RL	RFW16220	RFB11650RL	RFA17587
RFB09140	RFB09140M	RFB09140RL	RFB10200	RFE24600	RFL15000	RFW16220M	RFW16400	RFA17900
RFB09115P	RFB09115PM	RFB09115PRL	RFB10200M	RFM23000	RFL15000M	RFW16220RL	RFW16400M	RFL15087
RFB09140P	RFB09140PM	RFB09140PRL	RFB10200RL	RFM23000M	RFL15000RL	RFW16550	RFW16400RL	RFL15600
RFB09315	RFB09315M	RFB09315RL	RFB10300M	RFM23000M	RFL18115	RFW16550M	RFA17400	RFL15900
RFB09340	RFB09340M	RFB09340RL	RFB10300RL	RFM23000RL	RFL18140	RFW16550RL	RFA17400M	RFW15100
RFB09315P	RFB09315PM	RFB09315PRL	RFW16100	RFA17200	RFL18115M	RFK01111	RFA17400RL	RFW16000
RFB09340P	RFB09340PM	RFB09340PRL	RFW16100M	RFA17200M	RFL18140M	RFK01222	RFM61010	RFW16087
RFB10060	RFB10060M	RFB10060RL	RFW16100RL	RFA17200RL	RFL18115RL	RFK01201	RFS17NYL	RFW16087L
RFB10115	RFB10115M	RFB10115RL	RFY21000	RFA17210M	RFL18140RL	RFK01202	RFS16NYL	RFW16587
RFB10140	RFB10140M	RFB10140RL	RFY21500	RFA17210RL	RFW16200	RFK00100	RFB55095	RFW16900
RFY21610	RFY21610M	RFY21610RL	RFY21000M	RFA17220	RFW16200M	RFK00300	RFB55115	RFW16905
RFBAG115	RFBAG115M	RFW16683	RFY21500M	RFA17220M	RFW16200RL	RFK00400	RFB55135	RFW16910
		RFA17683		RFA17220RL	RFW162100	RFK00433	RFP11000	RCP01235
						RCP01100	RCP01236	RCP01238

Product reference with M and RL signify initial reference provided with lock either mechanic (RL) or magnetic (M)

have been classified as medical devices

- Class I
- in accordance with Annex IX, rule 1
- **state** that these devices are in conformity with essential requirements and Directive 93/42/EEC related to medical devices,
- **and** are subject to the procedure set out in Annex VII of Directive 93/42/EEC concerning medical devices,
- **and** comply with the following list of standards
- EN ISO 13485:2016 - Quality management systems — Requirements for regulatory purposes
- EN ISO 14971:2012 - Medical devices — Application of risk management to medical devices
- EN ISO 10993-1:2019 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- EN 1041: 2008+A1 - Information supplied by the manufacturer of medical devices
- EN ISO 15223-1:2016 - Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 62366:2008 Medical devices - Application of usability engineering to medical devices



Olivier Jonckers  
Managing Director

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