

EC - DECLARATION OF CONFORMITY


In compliance with (EU) 2017/745 Medical Device Regulation

Product name	Rollator
REF	RL200
Basic UDI-DI	3800501345955
MP Class and Rule	Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745
UMDNS	18306
Standards	EN ISO 14971:2019 EN ISO 15223-1:2022 EN 1041:2008+A1: 2014 ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN ISO 11199-2: 2005
Conformity Assessments	Annex II+III of Medical Devices Regulation (EU) 2017/745

We herewith declare that the above mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above Regulations by bearing CE-marking.



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