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EC – Declaration of Conformity

Manufacturers Name:	Orfit Industries N.V.
SRN (Single Registration Number):	BE-MF-000007872
Manufacturers Address:	Vosveld 9a, 2110 Wijnegem, Belgium
Basic UDI-DI:	5420028700114P
Name of the Device(s):	Orfit® Classic
Intended use:	For the fabrication of orthoses, external immobilisation devices and rehabilitation aids
Product code(s):	8332.SO1, 8332.SO2, 8333.SO1, 8333.SO2, 8333.SO2+, 8333.SO3, 8333.SO4, 8338.SO2, 8334.SO1, 8334.SO3, 8334.SO4, 8354.SO1, 8354.SO3, 8354.SO4, 8334.ST1, 8334.ST4, 8354.ST1, 8354.ST4, 8355.SO1, 8355.SO4, 8355.ST1, 8355.ST4, 35810, 35811, 35812, 35900, 35901, 35902, 35814, 35815, 35816, 35830, 35831, 35832, 35818, 35820, 35821, 35822, 35850, 35851, 35852, 35870, 35871, 35872, 35910, 35911, 35912, 35840, 35841, 35842, 35817KL, 35817KR
Classification:	Class I, according the rules of Annex VIII
Conformity assessment route:	Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to Annex IV.
Applied norms:	ISO 13485:2016 ISO 14971:2019 ISO 15223-1:2021 ISO 10993-5:2009 ISO 10993-10:2010

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by LRQA.
All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 29 May 2024

Quality Assurance & Regulatory Affairs Manager

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