

EC – Declaration of Conformity

Manufacturers Name: Orfit Industries N.V.

SRN (Single Registration Number): Pending until EudaMed implementation

Manufacturers Address: Vosveld 9a, 2110 Wijnegem, Belgium

Basic UDI-DI: 0542002870025MP

Name of the Device(s): MammoRX®

Product code(s): CHB-1, CHO-1, CHT-1, CHS-1, CHD-1, CBA-1, CBS-2, 33170, 33176, 33178, 32145/5, 32145/6, CFB-001/EU, CFB-003/EU, CFB-004/EU, CFB-005/EU, CFB-006/EU, CFB-001, CFB-003, CFB-004, CFB-005, CFB-006, CFB-001/MR, CFB-003/MR, CFB-004/MR, CFB-005/MR, CFB-006/MR, CFB-001/EU/NG, CFB-003/EU/NG, CFB-004/EU/NG, CFB-005/EU/NG, CFB-006/EU/NG

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:

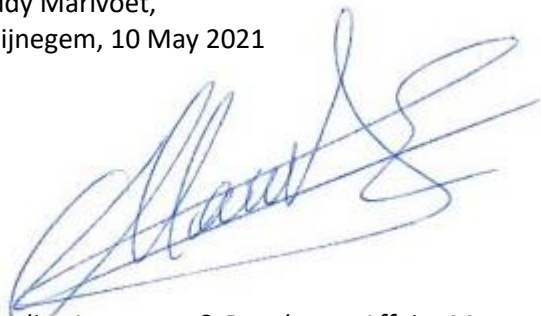
Class I: EC conformity declaration according to Annex IV.

Applied norms: ISO 13485:2016
NBN ISO 14971: 2012
ISO 14971:2007
ISO 15223-1:2016 Corrected version 2017-03
ISO 10993-5:2010
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 Lloyd's Register EMEA – LRQA.

All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 10 May 2021



Quality Assurance & Regulatory Affairs Manager