



EC – Declaration of Conformity

We hereby declare that for the products listed below Orfit Industries NV is in compliance with the directive 93/42/EC of the European Community and that it fulfills all the essential and other requirements put forward in the directive with respect to medical devices of class 1.

MammoRX[®] Carbon Fibre Breast Immobilization Systems

CHB-1	39320	CFB-001/EU	CFB-001/MR
CHO-1	33177	CFB-003/EU	CFB-003/MR
CHT-1	33170	CFB-004/EU	CFB-004/MR
CHS-1	33176	CFB-005/EU	CFB-005/MR
CHD-1	33178	CFB-006/EU	CFB-006/MR
CBA-1	32145/5	CFB-001	CFB-001/EU/NG
CBS-2	32145/6	CFB-003	CFB-003/EU/NG
		CFB-004	CFB-004/EU/NG
		CFB-005	CFB-005/EU/NG
		CFB-006	CFB-006/EU/NG

Product description:

Non active, noninvasive medical device class 1.
Positioning accessories for patient immobilization in radiotherapy.

Applied norms:

Directive 93/42/EC ISO 13485
 ISO 10993
 ISO 14971

Per annex VII of the Royal Decree of 18/03/1999 for Medical Devices.

Eddy Marivoet,
Wijnegem, 19 June 2019

Quality Assurance & Regulatory Affairs Manager