



**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**

		<u>Packages</u>	<u>Packages</u>
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-001	CFB-001/EU/NG
CBA-1		CFB-003	CFB-003/EU/NG
CBS-2		CFB-004	CFB-004/EU/NG
		CFB-005	CFB-005/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, 22 August 2018

*Quality Assurance & Regulatory Affairs Manager*