orfit Leader in thermoplastic innovations

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

		Packages	Packages
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-006/MR**
CBA-1	**32145/5**	**CFB-003**	**CFB-001/EU/NG**
CBS-2	**32145/6**	**CFB-004**	**CFB-003/EU/NG**
		CFB-005	**CFB-004/EU/NG**
		CFB-006	**CFB-005/EU/NG**
			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 February 2019

Quality Assurance & Regulatory Affairs Manager

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