



Version: 1.0

EU Declaration of Conformity

Date: XX/XX/2017

Declaration of Conformity for EMBRACE

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Embrace
Legal Manufacturer: (Name on Label)	Bionix Radiation Therapy, LLC 5154 Enterprise Boulevard Toledo, OH 43612 United States of America
Variants:	See product listing as per attached Annex
Intended Use:	Embrace allows reproducible and comfortable positioning of the patient receiving a course of radiation therapy.
MD Directive Classification:	Class I per Section III, Rule 5, Annex IX of the Medical Device Directive
Notified Body:	Not Applicable for Class I
EU Authorised Representative:	Advena Limited. Pure Offices, Plato Close, Warwick CV34 6WE United Kingdom
Medical Device Directive Assessment Route:	Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market.

Name Martin Singer Position Regulatory Affairs Manager

Signed *Martin Singer* Date 22/06/2017

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacture's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

CÔNG TY BẢN CHÍNH



GIÁM ĐỐC

LÝ THỂ VINH

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC

ANNEX – Product Listing/Schedule

Part/ Catalogue Number	Description/Name	GMDN Code	Part/ Catalogue Number	Description/Name	GMDN Code
EMRT-8300	2.4MM 10X10 STANDARD U-FRAME	58757	EMRT-8380	2.4MM HEAD & SHOULDER S-TYPE	58757
EMRT-8305	2.4MM 10X12 EXTENDED U-FRAME	58757	EMRT-8385	3.2MM HEAD & SHOULDER S-TYPE	58757
EMRT-8310	3.2MM 10X12 STANDARD U-FRAME	58757	EMRT-8400	2.4MM PERF: 18X24 PUNCHED ON 18" SIDE	58757
EMRT-8315	3.2MM 10X12 EXTENDED U-FRAME	58757	EMRT-8405	2.4MM SOLID: 18X24 PUNCHED ON 18" SIDE	58757
EMRT-8320	3.2MM 10X10 ADVANTAGE U-FRAME	58757	EMRT-8410	3.2MM PERF: 18X24 PUNCHED ON 18" SIDE	58757
EMRT-8325	3.2MM 10X12 EXTENDED SECUREFRAME	58757	EMRT-8415	3.2MM SOLID: 18X24 PUNCHED ON 18" SIDE	58757
EMRT-8330	2.4MM HEAD ONLY SECUREFRAME	58757	EMRT-8420	2.4MM PERF: 12X12	58757
EMRT-8335	2.4MM HEAD ONLY VERSAFRAME	58757	EMRT-8425	3.2MM PERF: 12X12	58757
EMRT-8340	3.2MM HEAD ONLY VERSAFRAME	58757	EMRT-8430	EXTREMITY THERMOPLASTIC SHEETS	58757
EMRT-8345	3.2MM HEAD & SHOULDER SECUREFRAME	58757	EMRT-8440	3.2MM PERF: 18X24	58757
EMRT-8350	2.4MM HEAD & SHOULDER VERSAFRAME	58757	EMRT-8450	2.4MM PERF: 9X12 PUNCHED ON 9" SIDE	58757
EMRT-8355	3.2MM HEAD & SHOULDER VERSAFRAME	58757	EMRT-8455	3.2MM PERF: 9X12 PUNCHED ON 9" SIDE	58757
EMRT-8360	3.2MM HEAD ONLY S-TYPE SECUREFRAME	58757	EMRT-8740	2.4MM HEAD ONLY FRAME & 8332-10 POSTERIOR FRAME	58757
EMRT-8365	2.4MM HEAD ONLY S-TYPE	58757	EMRT-8723	HEAD ONLY O-TYPE DISPOSABLE FRAME ASM	58757
EMRT-8370	3.2MM HEAD ONLY S-TYPE	58757	EMRT-8725	HEAD & SHOULDERS O-TYPE DISPOSABLE FRAME ASM	58757
EMRT-8375	3.2MM HEAD & SHOULDER S-TYPE SECUREFRAME	58757	EMRT-8740	2.4MM HEAD ONLY FRAME & 8332-10 POSTERIOR FRAME	58757
HNRT-8100K	SILVERMAN HEAD RESTS A – K FOR BIONIX BOARDS	58757	HNRT-8200K	TIMO HEAD RESTS A – K FOR BIONIX BOARDS	58757
HNRT-8120	SILVERMAN HEAD RESTS A FOR BIONIX BOARDS	58757	HNRT-8201	TIMO HEAD RESTS A FOR BIONIX BOARDS	58757
HNRT-8121	SILVERMAN HEAD RESTS B FOR BIONIX BOARDS	58757	HNRT-8202	TIMO HEAD RESTS B FOR BIONIX BOARDS	58757
HNRT-8122	SILVERMAN HEAD RESTS C FOR BIONIX BOARDS	58757	HNRT-8203	TIMO HEAD RESTS C FOR BIONIX BOARDS	58757
HNRT-8123	SILVERMAN HEAD RESTS D FOR BIONIX BOARDS	58757	HNRT-8204	TIMO HEAD RESTS D FOR BIONIX BOARDS	58757
HNRT-8124	SILVERMAN HEAD RESTS E FOR BIONIX BOARDS	58757	HNRT-8205	TIMO HEAD RESTS E FOR BIONIX BOARDS	58757
HNRT-8125	SILVERMAN HEAD RESTS F FOR BIONIX BOARDS	58757	HNRT-8206	TIMO HEAD RESTS F FOR BIONIX BOARDS	58757





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Version History

Version	Compiled by	Date	Description
1.0	Martin Singer	22/06/2017	First issue

