



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.

**Raycast® High Precision
Base Plate-To-Couch Fixation Devices**

32154	32002	32156	33141	35745
32166	32126	33146	33165	33124
32151	32813	32172	33129	33143
32191	32317/16	32184	32169	33142
32165	32066	32155	32182	33154
32190	33167	32178	32173	33155
35744/6	32822	33134	32174	33156
33109	32045	33159	32185	33166
33119	32810	35154	32179	33144
35747	32160	33133	33148	33145
35747/6	32165/6	33158	33140	33136
32063	32814	33139	33164	32158
35747/4	32815	32157	33138	33126
35747/8	32816	33150	33162	33125
32001	32817	33149	33153	33147
32000	32171	33131	33121	32207
32181	32183	33132	33120	32209
32070/17	32127	33123	33122	33173
		32208	33106	33168

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, 20 March 2018

Quality Assurance & Regulatory Affairs Manager