

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 Plates

32110	32150/HX	32124/MR
32111	32148	32110/MR
32113	29099	32809
32113MR	32110/7	32110/12
32117	32110/8	32130-COMBI1
32117MR	32110/9	32110-COMBI1
29102	32044	32150-COMBI1
32064	35751N	32130-COMBI2
29105	35754/6N	32110-COMBI2
32130	32122	32150-COMBI2
32140	32123	35751N-COMBI1
32150	32124	35751N-COMBI2
32150-PED	32130/MR	35754/6N-COMBI
32150/3	35702/2	35702/4
32110/12	32130/12	32140/12
32150/12		

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, 15 May 2019

Quality Assurance & Regulatory Affairs Manager