



**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.

**Raycast® High Precision
Efficast® Masks for Head, Neck and Shoulder Fixation for Push-Pin Hardware
Hybrid masks**

33747/16MI/NH
33780/16MI/12MI+N
33747/2MA/12MI+N
33747/2MA/12MI+N/NH
33755/16MI/NH
33781/16MI/12MI+N
33739/2MA/12MI+N
33739/2MA/12MI+N/NH
33755/2MA/12MI+N
33755/2MA/12MI+N/NH
33784/16MI/12MI+N

33766/2MA/12MI+N/NH
33786/16MI/12MI+N
33777/2MA/12MI+N/NH
33788/2MI/12MI+N

32199

Product description: Non active, noninvasive medical device class1.
Thermoplastic material, precut or in sheet form for patient
Immobilization in radiotherapy.

Per annex VII of the Royal Decree of 18/03/1999 for Medical Devices.

Applied norms: Directive 93/42/EC ISO 10993
ISO 13485
ISO 14971

Eddy Marivoet,
Wijnegem, 15 November 2018

Quality Assurance & Regulatory Affairs Manager