

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
Masks for Extracranial Immobilization**

33715/2MA
33716/2MA
33775/2MI/12MI+N
33683/32MA
33788/2MI/12MI+N
35727/32MA
35728/32MA
35790/2MA
33723/32MA/L
33723/32MA/R
33778/2MA/NP
35797/2MA/NP
35788/32MA
35787/32MA

35784/32MA
35780/32MA
35710/32MA
35711/32MA
35712/32MA
33774/2MA/12MI+N
35792/32MA
35793/32MA
35794/2MI
35795/2MI
35796/2MI
33717/2MA
33724/32MA
35799/2MI/R
35799/2MI/L

Product description:

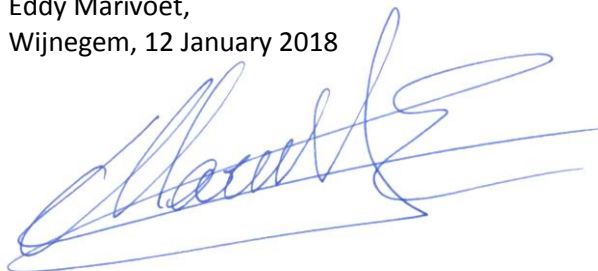
Non active, noninvasive medical device class1.
Thermoplastic material, precut or in sheet form for patient
Immobilization in radiotherapy.

Applied norms:

Directive 93/42/EC ISO 10993
 ISO 13485
 ISO 14971

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

Eddy Marivoet,
Wijnegem, 12 January 2018



Quality Assurance & Regulatory Affairs Manager