



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®
Duon™
Masks for Head and Neck**

**60120
60119
60122
60124
60121
60123
60001
60002
60001/EFF2MA
60125**

60098

Product description:

Non active, noninvasive medical device class 1.
Thermoplastic material, precut or in sheet form 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, 25 January 2018

Quality Assurance & Regulatory Affairs Manager