



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®
Uon™ - Duon™
Masks for Head and Neck**

- | | | |
|--------------|---------------------|--------------|
| 60110 | 60120 | 60098 |
| 60112 | 60119 | |
| 60114 | 60122 | |
| 60117 | 60124 | |
| 60095 | 60121 | |
| 60097 | 60123 | |
| | 60001 | |
| | 60002 | |
| | 60001/EFF2MA | |
| | 60125 | |

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, 2 February 2018

Quality Assurance & Regulatory Affairs Manager