



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.

SCISSORS & ACCESSORIES

35067
35061
35066
35065
35064
35140
35134
35137
35307
35307B10
35307B20
35003G
35003W
35003Z
35003G/1
35003W/1
35003Z/1
35105

Product description:

Non active, noninvasive medical device class 1.

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, 20 February 2018

Quality Assurance & Regulatory Affairs Manager

