



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.

Splint Padding and Lining Materials

35110
35112
35111
35117
360201N.ST1
35116

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, 19 November 2018

*Quality Assurance & Regulatory Affairs
Manager*