



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.

Hook and Loop Tape

35400L	35414L	35444L
35411L	35416L	35407H
35401L	35400H	35408H
35404L	35411H	35414H
35402L	35413H	35416H
35403L	35415H	35437L
35413L	35405H	35439L
35415L	35412H	35438L
35405L	35406H	35440L
35412L	35409H	35450
35432L	35443L	35455
	35444H	35460

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, 8 May 2018

Quality Assurance & Regulatory Affairs
Manager