

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	35406H	35416H
35411L	35409H	35442H
35401L	35407H	35444L
35404L	35408H	35444H
35402L	35413L	35437L
35403L	35415L	35439L
35405L	35441L	35432L
35412L	35414L	35438L
35400H	35416L	35440L
35411H	35413H	35443L
35405H	35415H	35450
35412H	35414H	35455
		35460

Product description:

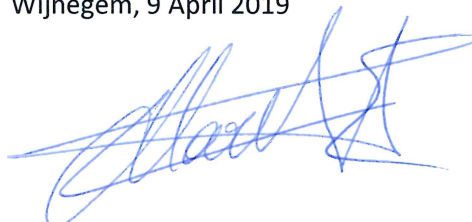
Non active, noninvasive medical device class 1.

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, 9 April 2019



Quality Assurance & Regulatory Affairs
Manager