



EC DECLARATION OF CONFORMITY

We,

WestCare (a trade name of SteveMedics b.v.)

Van Tuyll van Serooskerkenweg 45-3

1076 JC Amsterdam

The Netherlands

hereby declare under our sole responsibility that the CE marked product to which this declaration relates,

STEVE+

WestCare uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:

Class I

has been classified as Class I according to Annex IX rule 1, and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC)

and (are)(is) in conformity with the relevant harmonized standards EN ISO 10993-1

and is subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC (as amended by Directive 2007/47/EC)

Devices that are covered by this declaration of conformity are added on the [STEVE+]

Product reference list (see Annex).

Signature:

Date: 1-6-2020

Place: Amsterdam, The Netherlands

Name: Steven Westerbos

Function: CEO

Annex Product reference list

Name	Product name	Article number	Classification
Steve+	Donning and Doffing aid	ST1119822014, ST119822014, ST219822014, ST319822014	I
Steve+ easyON	Donning aid	A1119822014, A119822014, A219822014, A319822014	I
Steve+ easyOFF	Doffing aid	SEO1119822014, SEO119822014, SEO219822014, SEO319822014	I
Steve+ Ring	Doffing aid	R1119822014 R119822014 R219822014 R319822014	I