

EG VERKLARING VAN OVEREENSTEMMING

EC DECLARATION OF CONFORMITY

Ondergetekende,
The undersigned,

Firmanaam / Company name	Motek Medical BV
Single registration number (SRN):	Not yet allocated
Bezoekadres / Visiting address	Vleugelboot 14
Verzendadres / Postal address	Vleugelboot 14
Postcode / Postal code	3991 CL
Plaats / City	Houten
Land / Country	The Netherlands
Telefoon / Telephone	+31 88 633 42 00
Fax	+31 88 633 42 01

Verklaart als fabrikant geheel onder zijn eigen verantwoordelijkheid, dat de medische hulpmiddelen:
Being the manufacturer, declares under his sole responsibility that the medical devices:

Product naam / Device name	C-Mill; C-Mill VR; C-Mill VR+; C-Mill HERO
Model nummer / Model number	SY010, SY011, SY012, SY017
Accessoires / Accessories:	BWS Light (C-Mill VR+)
Basic (UDI-DI):	87193268410CMillJ4
Beoogde Doel / Intended Purpose	The C-Mill is an instrumented treadmill intended to evaluate human gait and balance and to train (impaired) gait and balance using treadmill movement, augmented reality and/or virtual reality
Klasse / Class (rule)	Class 1 (rule 13)
Notified body (ID) (if applicable)	NA
CE Certificate Notified Body (if applicable)	NA
CE Conformity assessment route:	Annex IX of 2017/745
Common specification (CS) (if applicable)	NA
Declaration valid from serial number:	SY010-40253-0001, SY010-40479-0001, SY011-40491-0001, SY011-40513-0002, SY011-40515-0001, SY011-40516-0002, SY012-40517-0001, SY012-40622-0002, SY012-40632-0001, SY012-40633-0009, SY017-47330-0010

waarop deze verklaring betrekking heeft, in overeenstemming is met de bepalingen van de Verordening Medische Hulpmiddelen (VMH) 2017/745.
to which this declaration relates is in conformity with the provisions of the Medical Devices Regulation (MDR) 2017/745 which apply to it.

Date: 26-05-2021

Date: 26-05-2021

Signature



Signature



Name: Patrick Broeksteeg

Name: Michael Smits

Function: Person Responsible for Regulatory Compliance

Function: General Manager