DECLARATION OF CONFORMITY

We, the manufacturer

Opitek International ApS, Gøngehusvej 252, 2950 Vedbæk, Denmark (Org. number: 30554582 - SRN: DK-MF-000001594)

declare that the following product(s):

Name of product / article	Article	UDI-DI
	number	
Electrical Leg & Arm Lift	2009-01	5714834000161-2009-01
Lift String, upholstered	2006-50	5714834000130-2006-50
Lift String, with Velcro lock	2006-60	5714834000123-2006-60
Velcro pad for 2006-60	2006-65	5714834000116-2006-65
String set:1 pcs 2006-70-1 + 1 pcs. 2006-60	2006-70	5714834000147-2006-70
Lift String, wide upholstered	2006-70-1	5714834000154-2006-70-1

Is (are) in conformity with the provisions of the following:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Classification according to Annex VIII, Chapter III, 4.1 Medical Device Class I: Non-invasive devices

Certification according to and in compliance with Annex I, II and IV

Issued under the sole responsibility of the manufacturer

Place: Vedbæk, Date: December 20, 2021

Peter Christensen CEO, Managing Director Opitek International ApS



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