

DECLARATION OF CONFORMITY

We, the manufacturer

Opitek International ApS, Gøngehusvej 252, 2950 Vedbæk, Denmark
(Org. Number / EORI number: DK30554582)

declare that the following product(s):

Name of product / article	Article number(s)	UDI-DI
PediStirrup Pediatric Leg Support, Complete system Left and right base (OR table support), 2 rail clamps, 5 pairs of shoes, 2 laser pointers	1111247	5714834000246-1111247
Velcro fixation strap, set w/8 pcs., single use. For PediStirrup shoe 1+2, 220mm	0871900001-T	5714834000277-0871900001
Velcro fixation strap, set w/12 pcs., single use. For PediStirrup shoe 3+4, 300mm	0871900002-T	5714834000284-0871900002
Velcro fixation strap, set w/6 pcs., single use. For PediStirrup shoe 5, 350mm	0871900003-T	5714834000291-0871900003

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**

Issued under the sole responsibility of the manufacturer

Place: Vedbæk, **Date:** November 30, 2021



Peter Christensen
CEO, Managing Director
Opitek International ApS

