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 number(s)**	**UDI-DI**
Hip Fix, all models	*1900-01, 2000-182, 2015-200, 1915-200, 2015-200+8 & upgrades hereof (x-100)*	5714834000260-1900-01 5714834000055-2000-182 5714834000185-2015-200 5714834000208-1915-200 5714834000178-2015-100 5714834000192-1915-100
Hip Fix pads, multiple use	2000-01, 2000-02	5714834000079-2000-01 5714834000062-2000-02
Hip Fix Pads, single use, 3 support cushions (patient pack)	2015-50-1	5714834000215-2015-50-1

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

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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