

## EC – Declaration of Conformity

**Manufacturers Name:** Orfit Industries N.V.

**SRN (Single Registration Number):** Pending until EudaMed implementation

**Manufacturers Address:** Vosveld 9a, 2110 Wijnegem, Belgium

**Basic UDI-DI:** 0542002870030MG

**Name of the Device(s):** The AIO Solution® (All-in-One Patient Positioning Solution)

**Product code(s):** 38001, 38002, 38005, 38006, 38008, 38003, 38007, 38004, 38100, 38101, 38102, 38126, 38127, 38128, 38200, 38201, 38202, 38203, 38204, 38205, 38213, 38206, 38210, 38211/6, 32204-PED, 32301, 32301/NOLS, 32301-PED, 32301-PED/NOLS, 32301-PED/SS, 32301-PED/SS/NOLS, 32301/HX, 32301/MR, 35754/6N, 32140/12, 29007-V2, 29008-V2, 29009-V2, 29010-V2, 29011-V2, 29012-V2, 29013-V2, 29014-V2, 29015-V2, 29016-V2, 29017-V2, 29018-V2, 29019-V2, 29112-V2, 29000-V2, 29003-V2, 29004-V2, 29005-V2, 29006-V2, 32054-V2, 29001-V2, 29002-V2, 29020-V2, 29023-V2, 29024-V2, 29025-V2, 29021-V2, 29022-V2, 32015/10, 32015/5, 29057, 29058, 29059, 38103, 38106, 38125, 38126, 38116, 38208, 38107, 38108, 38109, 38216, 38223, 38009

**Classification:** Class I, according the rules of Annex VIII

**Conformity assessment route:** Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Annex IV.

**Applied norms:** ISO 13485:2016  
NBN ISO 14971: 2012  
ISO 14971:2007  
ISO 15223-1:2016 Corrected version 2017-03  
ISO 10993-5:2010  
ISO 10993-10:2010

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by Lloyd's Register EMEA – LRQA. All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,  
Wijnegem, 7 May 2021

Quality Assurance & Regulatory Affairs      Manager