X6 INNOVATIONS

EU Declaration of Conformity

Manufacturer Name: X6 Innovations SAS

Manufacturer Address: 128 Rue La Boétie, 75008, Paris, France

Name of Medical Product: Perifit Care+

GMDN Code: 46624 (Pelvic floor muscle exerciser)

Basic UDI : 3770014642PER002V7

UDI-DI: GTIN: 03770014642172

UMDNS: 15220 (Exercisers, Other)

Class of Medical Product: Class I

EU MDR 2017/745, Annex VIII Rule: Rule 5

Software Classification according to IEC 62304: Class A

We herewith declare under our sole responsibility that the Medical Device referenced above meets the provisions of Regulation (EU) 2017/745 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. It also meets the provisions of Directive 2014/53/EU (RED), Directive 2013/30/EU (EMC), Directive 2014/35/EU (LV), Directive 2012/19/EU (WEEE), Directive EC 1907/2006 (REACH), Directive 2011/65/EU (RoHS).

Applied harmonised standards for the Regulation (EU) 2017/745:

- ISO 13485/A11:2021
- ISO 15223-1:2021
- EN ISO 14971:2019/A11:2021
- ISO 10993-23:2021

Other applied standards:

- ISO 20417:2021
- IEC 62366-1:2015/A1:2020
- IEC 62304:2006/A1:2015
- EN 60601-1:2006/A1:2013/A2:2021
- EN 60601-1-2:2016
- EN 60601-1-6:2010
- IEC 60601-1-11:2015
- ISO 10993-1:2018
- ISO 10993-5:2009
- ISO 10993-10:2021
- ISO 10993-11:2017
- IEC 60529:1989/A1:1999/A2:2013

Place and Date of issue: Paris, France, 20/07/2023

Signed for and on behalf of: X6 Innovations

Name and Role of Authorized Signatory: Erica Perrier, PhD, Head of R&D and Regulatory Affairs



_____

(Signature)