

EC DECLARATION OF CONFORMITY

Manufacturer: VITABALANS Oy
Varastokatu 8
13500 Hämeenlinna
Finland

Conformity Assessment Procedure: Annex II of Medical Device Directive 93/42/EEC

Identification of Notified Body: Eurofins Expert Services
Kivimiehentie 4
FI-02150 Espoo
Finland
Notified Body EC Code no. 0537

Identification of EC-certificate: Certificate no. C-01-1130-684-19

References to the relevant harmonised standards and similar documents used: ISO 13485:2016
ISO 14971:2019
Medical Device Directive 93/42/EEC

Identification of Device: Name: MacroBalans
MacroLedin
Category: Medical Device for prevention and alleviation of constipation
Class: Type IIa (MDD 93/42/EEC)

We, the manufacturer hereby declare that the above-mentioned medical device comply the relevant provisions of EU Council Directive 93/42/EEC dated 14 June 1993 as amended by directive 2007/47/EC - Essential requirements and its relevant transpositions into national laws of the Member States in which the above-mentioned medical device is distributed.

Place and date: Hämeenlinna, 3rd July 2020



Satu Virtanen
Qualified Person
Vitabalans Oy