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:**	Asept
Gategory:	Disinfectants for skin
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 of July 2020

Satu Virtanen
Qualified Person
Vitabalans Oy