

## 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 and Dsept  
**Category:** 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, 11<sup>th</sup> of May 2021

  
Satu Virtanen  
Qualified Person  
Vitabalans Oy

  
Marjo Volotinen-Maja  
Director of RA&PD, QPPV  
Vitabalans Oy