EU-Declaration of Conformity

1. Name and address of the manufacturer

Company name: NE Device SW
Postal address: Teknologiantie 7 B
Postcode and city: FIN-90590 Oulu
Phone number: +358 50 4868749
Email address: info@nedevicesw.com

2. Object of declaration:

product: Vitacam,
Version: 0.10.1
Class: Medical device classification lla according to rule 10 set out in Annex IX of Directive 93/42/EEC
GMDN: 64339, Cardiopulmonary physiologic analysis software

3. NE Device SW Oy declares under its sole responsibility that the object of the declaration described above is in conformity with the relevant Union harmonization legislation:

Provisions of Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices.

4. References to the relevant harmonized standards used or references to the other technical specifications in relation to which conformity is declared:

EN ISO 13485:2016 Medical devices --Quality management systems --Requirements for regulatory purposes

SFS-EN ISO 14971:2019 Medical devices. Application of risk management to medical devices

IEC 62366-1:2015 Medical devices –Part 1: Application of usability engineering to medical devices

IEC 62304:2015 Medical device software –software life cycle processes

SFS-EN ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information to be supplied.

5. Notified body:

SGS Fimko oy, (0598, Takomotie 8 ,00380, Helsinki)

has reviewed Vitacam's technical file, performed conformity assessment procedures as specified in Annex II (Full Quality Assurance System) and granted EC certificate FI21/871845.

Additional information

Signed behalf of NE Device SW
Time and Place: Oulu 20/05/2021
Authorized representative: Moyeen Ahmad, CEO

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Signature