

Declaration of Conformity

According to the EC – Medical Device Directive 93/42/EEC Annex VII

Manufacturer: Neuro Event Labs Oy

Biokatu 10

33520 Tampere

FINLAND

Product Name: Nelli

Product Classification: Class I, based on Annex IX rule 12

GMDN-Code: 61288

Fimea medical device registration number: FI-CA01-2020-0612

We, Neuro Event Labs Oy, hereby declare that the above product has been designed and manufactured in conformity with the applicable provisions of the European Directive 93/42/EEC.

The product fulfills

requirements of standard: EN ISO 13485:2016 Medical devices - Quality management systems -

Requirements for regulatory purposes

Signature: Tampere 16.6.2020

Kaapo Annala

CEC

Neuro Event Labs Oy

Kaye Auch