EC DECLARATION OF CONFORMITY

We,

Prolira BV
Padualaan 8
3584 CH
The Netherlands

hereby declare under our sole responsibility that the CE-marked products to which this declaration relates,

DeltaScan Monitor (Release 2)
Basic UDI-DI: 87193264653006.000P7

having the intended purpose:
to support the clinical assessment of delirium by providing a Delirium Probability based on electroencephalography (EEG) signals.

and have been classified as Class IIa, according to Annex VIII, Rule number 10,

and the software of the DeltaScan Monitor is considered as “Software driving or influencing the use of a device” per EU MDR, and falls in the classification IIa per EU MDR Rule 11 of Annex VIII Chapter III. In addition, Software, which drives a device or influences the use of a device, shall fall within the same class as the device, which is also IIa,

and are in conformity with the General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are covered by the EC Certificate, with reference number **19M00150CRT01**, first issued on **June 17, 2020** by DARE!! Medical Certifications (Notified Body Identification Number 1912), in accordance with Annex IX of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,

and are in conformity with the standards EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013 and EN 60601-1-2:2015, EN 1041:2008+A1:2013, EN 62304:2006+A1:2015, EN 62366-1:2015, ISO 14971:2012, and ISO 13485:2016.

and are in conformity with the requirements of directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Signature:

Utrecht, The Netherlands
Date: Jul 7, 2020
Name: Rutger van Merkerk
Function: CEO

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Final Audit Report 2020-07-07

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