EC DECLARATION OF CONFORMITY

The undersigned,

Legal Manufacturer:	LivAssured B.V.
Single registration number (SRN):	NL-MF-000022904
Address:	Schipholweg 103, 2316 XC, Leiden, The Netherlands

being the legal manufacturer, declares under his sole responsibility that the medical device:

Device name:	NightWatch
Basic UDI-DI:	87193261921NW014L
Intended Purpose:	NightWatch is intended to notify a caregiver of the occurrence of a patient's Nocturnal Epileptic Motor Seizures(*) in order to allow caregivers to take appropriate caring measures. *Nocturnal Motor Seizures, being the following seizure types : • Tonic-Clonic Seizures (Generalised and focal to bilateral) • Tonic (if cluster or prolonged) • Myclonic (if cluster) • Focal impaired awareness with hyperkinetic movements NightWatch is not intended for diagnosis or treatment purposes.
Declaration valid from:	Devices produced since 26th of May 2021

to which this declaration relates meets the provisions of the following European Union Reglations and Council Directives

Regulation:	Medical Device Regulation (EU) 2017/745
Common Specifications:	No specification availble for this device
MDR Classification (rule):	Class I (MDR Annex VIII rule 13)

Other Regulations/Directives:	Radio Equipment Directive 2014/53/EU ROHS Directive 2011/65/EU; annex II 2015/863 WEEE Directive 2012/19/EU Reach Regulation (EC) No 1907/2006

Chief Executive Officer (CEO)

Place: Schipholweg 103, 2316 XC, Leiden, The Netherlands
Date: 12th of August 2024

Signature:

Name: Jeroen van den Hout