EC DECLARATION OF CONFORMITY

The undersigned,

Legal Manufacturer:	LivAssured BV
Tradename Manufacturer:	NightWatch
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:

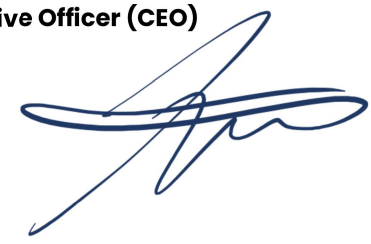
Device name:	NightWatch+
Basic UDI-DI:	8719327092NWMJZ
Intended Purpose:	NightWatch+ is intended to notify a caregiver of the occurrence of a patient's Nocturnal Epileptic Motor Seizures(*) and monitor seizure frequency over time. (*)Nocturnal Epileptic Motor Seizures, being the following seizure types: • Tonic-Clonic • Tonic (if clustered or prolonged) • Myclonic (if clustered) • Hyperkinetic
Declaration valid from manufacturing date:	31st of March 2025

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 IIa (MDR Annex VIII rule 10)
Notified body (ID) :	Slovenian Institute of Quality and metrology (1304)
Certificate No. Notified Body:	MDR-0027
Conformity assessment route:	Annex IX

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: Leiden
Signature:



Digitally signed on: 18th March 2025 10:45:20 (UTC/GMT +01:00 - Europe/Brussels)

Name: Jeroen van den Hout
Function: Chief Executive Officer

Person Responsible for Regulatory Compliance (PRRC)
Place: Leiden
Signature:

Digitally signed on: 18th March 2025 10:08:51 (UTC/GMT +01:00 - Europe/Brussels)

Name: Jolanda Oorthuizen
Function: Quality and Regulatory Affairs Manager