

EU DECLARATION OF CONFORMITY

Manufacturer

Philips North America LLC
222 Jacobs Street
Cambridge, MA 02141, USA

Product Identification

Product Name: Tablet

Product Models: Neuron 4 Connectivity Console 6S2E-8m, Neuron 4 Connectivity Console 6S2U-8m, Neuron 4 Connectivity Console 8S-8m, Neuron 4 Connectivity Console 2S-10l

Hardware Version(s): 1.0

Software/Firmware Version(s): AR13/CR24

Philips North America LLC hereby declares under its sole responsibility that the product identified above complies with the following Union harmonisation legislation.

Directive 2011/65/EU (RoHS)

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, including Commission Delegated Directive (EU) 2015/863.

Directive 2014/53/EU (RED)

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 relating to the making available on the market of radio equipment.

RED Conformity Assessment Procedure

The conformity assessment procedure described in Article 17 and Annex III of Directive 2014/53/EU has been applied. Module B (EU Type Examination) and Module C (Conformity to Type Based on Internal Production Control) have been performed.

Notified Body	Kiwa Nederland B.V.
Notified Body Number	0063
EU Type Examination Certificate Number	[Insert Certificate Number]
Assessment Modules	Module B + Module C

The Notified Body Kiwa Nederland B.V., Notified Body No. 0063, performed the EU Type Examination procedure (Module B) and issued the EU Type Examination Certificate referenced above.

Safety

- EN IEC 62368-1:2020+A11:2020
- EN IEC 62311:2020

EMC

- ETSI EN 301 489-1 V2.2.3
- ETSI EN 301 489-3 V2.3.2
- ETSI EN 301 489-17 V3.3.1
- EN 55032:2015/A1:2020
- EN 55035:2017/A11:2020
- EN IEC 61000-3-2:2019/A2:2024
- EN 61000-3-3:2013/A2:2021/AC:2022-01
- EN60601-1-2:2015/A1:2021

Radio Spectrum

- EN 300 328 V2.2.2 (2019-07)
- EN 301 893 V2.2.1 (2024-11)
- EN 300 440 V2.2.1 (2018-07)

RoHS

- EN IEC 63000:2018

Additional Regulatory Information

Neuron 4 is compliant with Directive 2011/65/EU, as amended by Commission Delegated Directive (EU) 2015/863. The restricted substances listed in Annex II are not present above the applicable maximum concentration values in homogeneous materials as specified by the Directive.

All supporting documentation is retained at the premises of the manufacturer.

Neuron 4 does not bear a CE mark under Regulation (EU) 2017/745 on medical devices (EU MDR) because it does not meet the definition of a medical device as set out in Article 2 of the Regulation. However, the product has been developed and manufactured in accordance with ISO 13485 and has been evaluated against IEC 60601-1 to ensure it can be safely integrated and used within medical electrical systems.

Authorized Signatory

Name	Khalid Merghich on behalf of Thiago Barbosa
Position	Certification lead
Date of Issue	8 August 2026
Signature	

DocuSigned by:

B6415139EA74491...

