Declaration of conformity (MDR)

We, Irisbond Crowdbonding Ltd, declare that the product listed below has been designed and manufactured in conformity with the Directive (UE) 2017/745:

MANUFACTURER	IRISBOND CROWDBONDING, SL ES-B75091058 AVENIDA DE TOLOSA, 75 - 2° San Sebastián, 20018 Guipúzcoa, Spain +34 9434 96 622 http://www.irisbond.com
REFERENCE	IRISBOND HIRU
PRODUCT	Eye tracking system HIRU

The aim of this declaration is a Class I Medical Device and is in conformity with the following harmonised legislation:

APPLICABLE DIRECTIVE	• Directive (UE) 2017/745 concerning medical devices, MDR. • EMC Directive, 2004/108/EC. • RoHS Directive, 2011/65/EU. • FCC Rules and Regulations.

The following harmonized standards and technical specifications have been applied:

HARMONIZED LEGISLATION	EN 55032 (2015) / AC (2016) / A11 (2020) EN 55035 (2017) UNE-EN 62471-1:2009 FCC CFR 47, Part 15, Subpart B (10-1-15 Edition) ICES-003 Issue 6 (2016)
TEST CERTIFICATES	65321IEM.001 65321REM.001 65321REM.002 2251989-PHO-21-018A

This declaration is signed on behalf of Irisbond Crowdbonding, Ltd in San Sebastián, on the 30th of April, 2021, by Eduardo Jauregui, CEO.

Declaration of conformity (MDR)

We, Irisbond Crowdbonding Ltd, declare that the product listed below has been designed and manufactured in conformity with the Directive (UE) 2017/745:

MANUFACTURER	IRISBOND CROWDBONDING, SL ES-B75091058 AVENIDA DE TOLOSA, 75 - 2° San Sebastián, 20018 Guipúzcoa, Spain +34 9434 96 622 http://www.irisbond.com
REFERENCE	OSKOL WINDOWS
PRODUCT	This product is composed by the following elements: • Medical device; Eye tracking system HIRU. • Case to bundle the Irisbond HIRU eye tracker and the Surface Pro tablet (TPU material has PASSED skin sensitization and cytotoxicity tests in accordance with ISO 10993-5 and 10993-10).

The aim of this declaration is a Class I Medical Device and is in conformity with the following directives:

APPLICABLE DIRECTIVE	**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, MRD**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directive 90/385/EEC.

The following harmonized standards and technical specifications have been applied:

HARMONIZED LEGISLATION	**HIRU:** EN 55032: 2015 / AC: 2016 / A11: 2020 EN 55035: 2017 UNE-EN 62471-1:2009 FCC CFR 47, Part 15, Subpart B (10-1-15 Edition) ICES-003 Issue 6: 2016 **OSKOL Windows:** ISO 10993-5 ISO 10993-10
TEST CERTIFICATES	65321IEM.001 65321REM.001 65321REM.002 2251989-PHO-21-018A

This declaration is signed on behalf of Irisbond Crowdbonding, Ltd in San Sebastián, on the 30th of April, 2021, by Eduardo Jauregui, CEO.

Declaration of conformity (MDR)

We, Irisbond Crowdbonding Ltd, declare that the product listed below has been designed and manufactured in conformity with the Directive (UE) 2017/745:

MANUFACTURER	IRISBOND CROWDBONDING, SL ES-B75091058 AVENIDA DE TOLOSA, 75 - 2° San Sebastián, 20018 Guipúzcoa, Spain +34 9434 96 622 http://www.irisbond.com
REFERENCE	OSKOL iPad
PRODUCT	This product is composed by the following elements: • Eye tracking system HIRU, medical device class I. • Case to bundle the Irisbond HIRU eye tracker and the iPad Pro tablet (TPU material has PASSED skin sensitization and cytotoxicity tests in accordance with ISO 10993-5 and 10993-10)

The aim of this declaration is a Class I Medical Device and is in conformity with the following harmonised legislation:

APPLICABLE DIRECTIVE	**REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 concerning medical devices, MDR**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directive 90/385/EEC.

The following harmonized and/or unharmonized standards and technical specifications have been applied:

HARMONIZED LEGISLATION	**HIRU:** EN 55032: 2015 / AC: 2016 / A11: 2020 EN 55035: 2017 UNE-EN 62471-1:2009 FCC CFR 47, Part 15, Subpart B (10-1-15 Edition) ICES-003 Issue 6: 2016 **OSKOL iPad:** ISO 10993-5 ISO 10993-10
TEST CERTIFICATES	65321IEM.001 65321REM.001 65321REM.002 2251989-PHO-21-018A

This declaration is signed on behalf of Irisbond Crowdbonding, Ltd in San Sebastián, on the 30th of April, 2021, by Eduardo Jauregui, CEO.