# EC DECLARATION OF CONFORMITY

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|---|---|
| ***Manufacturer SRN:*** | US-MF-000012443 |
| ***Manufacturer:*** | Foreseeson Custom Displays, Inc.<br>2210 E. Winston Road<br>Anaheim, CA 92806 USA |
| ***Authorized Representative SRN:*** | DE-AR-000005685 |
| ***Authorized Representative:*** | KTR Europe GmbH,<br>Mergenthalerallee 77,<br>65760 Eschborn, Germany |
| ***Model Number:*** | FM-E3230D, FM-E3230DG, FM-E3230DN |
| ***Product Description / Name:*** | 4K Color Display |
| ***Basic UDI-DI (GMN):*** | 081000089071YC |
| ***GMDN Code:*** | 36612 - Image display monitor, colour |
| ***EMDN Code:*** | Z11900802 - BIOIMAGING VIEWING MONITORS |
| ***UMDNS Code:*** | 15-969 - Television Systems, Operating Room |
| ***Conformity Assessment Route:*** | Foreseeson uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:<br>Class 1: EC conformity declaration according to MDR 2017/745 |

We, Foreseeson Custom Displays Inc., declare that the above-named product(s) conform to the essential requirements of the following European Union Directive(s):

- **Medical Device Regulation (EU) 2017/745**
- **EU RoHS Directive 2011/65/EU+2015/863/EU**

The following harmonized standards and specifications have been used and are listed by specific reference to the essential requirements of the referenced Directives:

EN 60601-1-2:2015 +A1:2021 / IEC 60601-1-2:2014 +A1:2020, EN 55011:2016 +A1:2017 +A2:2021 / CISPR 11:2015 +A1:2016 +A2:2019 (Group 1 Class B), EN IEC 61000-3-2:2019 / IEC 61000-3-2:2018, EN 61000-3-3:2013 +A1:2019 / IEC 61000-3-3:2013 +A1:2017, EN 61000-4-2:2009 / IEC 61000-4-2:2008, EN 61000-4-3:2006 +A1:2008+A2:2010 / IEC 61000-4-3:2006+A1:2007 +A2:2010, EN 61000-4-4:2012 / IEC 61000-4-4:2012, EN 61000-4-5:2014 +A1:2017 / IEC 61000-4-5:2014 +A1:2017, EN 61000-4-6:2014 /AC:2015 / IEC 61000-4-6:2013, EN 61000-4-11:2004 +A1:2017 / IEC 61000-4-11:2020

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013,IEC 60601-1-6:2010/AMD2:2020, EN 60601-1:2006, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1-6:2010, EN 60601-1-6:2010/A1:2015, EN 60601-1-6:2010/A2:2021

**EU RoHS Directive 2011/65/EU+2015/863/EU**

EN IEC 63000:2018

This declaration of conformity is issued under the sole responsibility of Foreseeson Custom Displays Inc. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by BSI Certificate No. FM 655810. All supporting documentation is retained at the premises of the manufacturer.

*Signed on behalf of Foreseeson Custom Displays Inc.*

[redacted]

Regulatory Affairs Manager

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