

EC DECLARATION OF CONFORMITY

Manufacturer SRN: US-MF-000012443
Manufacturer: Foreseeson Custom Displays, Inc.
2210 E. Winston Road
Anaheim, CA 92806 USA

Authorized Representative SRN: DE-AR-000005685
Authorized Representative: KTR Europe GmbH,
Mergenthalerallee 77,
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:
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.

Foreseeson Custom Displays, Inc.

2210 E. Winston Rd.
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Robert Contreras

Regulatory Affairs Manager

Place of Issue: Foreseeson Custom Displays Inc., 2210 E. Winston Road, Anaheim, CA 91770 USA

Date of Issue: August 26, 2024