

DECLARATION OF CONFORMITY



WE: DESIN LLC

MANUFACTURER: DESIN LLC

MANUFACTURER'S AUTH. REP.

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HEREBY DECLARE THAT THE DEVICE:

DEVICE (MODEL):

DESCRIPTION

Obi (IFD-500-000)

Robotic Dining Device (Class I medical device, active, non-sterile, non-measuring)

GTIN (issued by GS1): 0869174000106

CONFORMS WITH THE FOLLOWING STANDARDS:

NUMBER

TITLE

ISO13485: 2016

Medical devices - Quality management systems - requirements for regulatory purposes

IEC60601-1: 2005

Medical electrical equipment - General requirements for basic safety and essential performance.

ISO 14971: 2019

Application of risk management to medical devices

IEC60601-1-2: 2014

Medical electrical equipment - Electromagnetic compatibility (EMC) for medical devices

IEC60601-1-6: 2010

Medical electrical equipment - Usability

IEC60601-1-11: 2015

Medical electrical equipment - Requirements for medical electrical equipment and medical electrical

systems used in the home healthcare environment

IEC62304: 2006

Medical device software - Software life cycle processes

NEN EN 15284: 2007

Materials and articles in contact with food stuffs. Test method for the resistance to microwave

heating of ceramic, glass, glass-ceramic or plastic cookware.

EN50581:2012

Technical documentation for the assessment of electrical and electronic products with respect to the

restriction of hazardous substances

AND IF APPLICABLE, CONFORMS WITH THE FOLLOWING DIRECTIVES:

NUMBER

TITLE

MDR 2017/745

Medical Device Regulation Food Contact Directive

EC/1935/2004 . 2014/30/EU

Electromagnetic Compatibility (EMC) Directive

2014/35/EU

Low Voltage Directive

2015/863

RoHS3 Directive

2012/19/EU

WEEE2 Directive

93/68/EEC

CE Marking Directive

SIGNED AT:

Dayton, OH

ORIGINATED, REVIEWED AND APPROVED BY

NAME: Jon Dekar; CEO

DATE (MM/DD/YYYY):

3/17/2020

SIGNATURE: