

# **DECLARATION OF CONFORMITY**

WE: DESTN LLC

MANUFACTURER: DESTN LLC

MANUFACTURER'S AUTH, REP.

Focal Meditech BV

ADDRESS: 714 E. Monument Ave

ADDRESS:

Droogdokkeneiland 19

5026SP Tilburg Netherlands

Dayton, OH 45402 TEL: 248-766-2085 FAX: 248-858-9076

WEBSITE: www.meetobi.com

E-mail Jdekar@desincorp.com

TEL: FAX: Tel.: +31 (0)13-533 31 03 Fax: +31 (0)13-533 50 04

E-mail

info@focalmeditech.nl

WEBSITE:

www.focalmeditech.nl

### HEREBY DECLARE THAT THE DEVICE:

**DEVICE (MODEL):** Obi (IFD-500-000)

DESCRIPTION

Robotic Dining Device

### CONFORMS WITH THE FOLLOWING STANDARDS:

NUMBER

TITLE

EN ISO 14971 R2012

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

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.

UL1431: 2011

Home healthcare and hygiene appliances

### AND IF APPLICABLE, CONFORMS WITH THE FOLLOWING DIRECTIVES:

NUMBER

TITLE

93/42/EEC EC/1935/2004 Medical Device Directive Food Contact Directive

2014/30/EU

Electromagnetic Compatibility (EMC) Directive

2014/35/EU

Low Voltage Directive

2011/65/EU

**RoHS Directive** 

2012/19/EU

WEEE Directive

93/68/EEC

**CE Marking Directive** 

SIGNED AT:

Dayton, OH

Jon Dekar: President

DATE:

8/15/2017

SIGNATURE:



## **DECLARATION OF CONFORMITY**

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Focal Meditech BV

ADDRESS: 7018 AC Skinner Parkway, Suite 270

ADDRESS:

Droogdokkeneiland 19 5026SP Tilburg

Jacksonville, FL 32256 **TEL:** 248-766-2085

TEL:

Netherlands

FAX: 248-858-9076

FAX:

Tel.: +31 (0)13-533 31 03 Fax: +31 (0)13-533 50 04

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info@focalmeditech.nl www.focalmeditech.nl

### 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 EC/1935/2004

Food Contact Directive

Medical Device Regulation

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

DATE SIGNED (MM/DD/YYYY):

1/6/2021

ORIGINATED, REVIEWED AND APPROVED BY:

NAME: Jon Dekar; CEO

SIGNATURE: