



DECLARATION OF CONFORMITY

WE: DESIN LLC

MANUFACTURER: DESIN LLC

MANUFACTURER'S AUTH. REP.

Focal Meditech BV

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E-mail Jdekar@desincorp.com
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E-mail info@focalmeditech.nl
WEBSITE: www.focalmeditech.nl

HEREBY DECLARE THAT THE DEVICE:

DEVICE (MODEL):	DESCRIPTION
Obi (IFD-500-000)	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	Medical Device Directive
EC/1935/2004	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:



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HEREBY DECLARE THAT THE DEVICE:

Table with 2 columns: DEVICE (MODEL): and DESCRIPTION. Row 1: Obi (IFD-500-000) and Robotic Dining Device (Class I medical device, active, non-sterile, non-measuring) GTIN (issued by GS1): 0869174000106

CONFORMS WITH THE FOLLOWING STANDARDS:

Table with 2 columns: NUMBER and TITLE. Lists standards such as ISO13485: 2016, IEC60601-1: 2005, ISO 14971: 2019, etc.

AND IF APPLICABLE, CONFORMS WITH THE FOLLOWING DIRECTIVES:

Table with 2 columns: NUMBER and TITLE. Lists directives such as MDR 2017/745, EC/1935/2004, 2014/30/EU, etc.

DATE SIGNED (MM/DD/YYYY): 1/6/2021

ORIGINATED, REVIEWED AND APPROVED BY:

NAME: Jon Dekar; CEO

SIGNATURE: