



DECLARATION OF CONFORMITY

WE: DESIN LLC

MANUFACTURER: DESIN LLC

MANUFACTURER'S AUTH. REP.

Focal Meditech BV

ADDRESS: 714 E. Monument Ave
Dayton, OH 45402
TEL: 248-766-2085
FAX: 248-858-9076
E-mail Jdekar@desincorp.com
WEBSITE: www.meetobi.com

ADDRESS: Droogdokkeneiland 19
5026SP Tilburg
Netherlands
TEL: Tel.: +31 (0)13-533 31 03
FAX: Fax: +31 (0)13-533 50 04
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: