DESIN LLC

DECLARATION OF CONFORMITY

MANUFACTURER: *DESiN LLC*
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MANUFACTURER'S AUTH. REP. *Focal Meditech BV*
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WE, DESiN LLC, UNDER OUR SOLE RESPONSIBILITY, HEREBY DECLARE:

DEVICE (MODEL):
Obi (IFD-500-030)

DESCRIPTION
Independent Eating Device (Class I Medical Device, Active, Non-Sterile, Non-Measuring)
BASIC UDI-DI: 086917400010bi34

CONFORMS WITH THE FOLLOWING STANDARDS:

NUMBER	TITLE
ISO13485: 2016	*Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes*
IEC60601-1: 2012	*Medical Electrical Equipment - General Requirements for Basic Safety and Essential Performance.*
ISO 14971: 2019	*Application of Risk Management to Medical Devices*
IEC60601-1-2: 2020	*Medical Electrical Equipment - Electromagnetic Disturbances - Requirements and Tests*
IEC60601-1-6: 2020	*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: 2015	*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*
EC/1935/2004	*Food Contact Directive*
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*

ORIGINATED, REVIEWED AND APPROVED BY:
Jon Dekar; *CEO, DESiN LLC*
SIGNATURE:
DATE (MM/DD/YYYY): 06/20/2023