EU DECLARATION OF CONFORMITY

1. Manufacturer	
Legal name	DESĪN LLC
Registered address	7018 AC Skinner Parkway, Suite 270, Jacksonville, FL 32256, USA
Manufacturer SRN	US-MF-000008647
2. Authorized Representative	
Legal name	Focal Meditech BV
Registered address	Droogdokkenland 19, 5026SP Tilburg, Netherlands
Authorized Representative SRN	NL-AR-000000549
3. Sole Responsibility	
Statement	This EU Declaration of Conformity is issued under the sole responsibility of DESĪN LLC.
4. Basic UDI-DI (GS1 GMN)	
Obi	08691740001Obi34
5. Device Identification	
Product / trade name	Obi
Device model / product code	Obi3 (third generation)
UDI-DI / GTIN - Obi3 (3rd Gen)	00869174000113
Reference/SKU/Catalogue No.	IFD-500-030
Intended purpose	Obi is a reusable robotic utensil intended to restore functional self-feeding—an essential activity of daily living.
6. Classification	
Annex VIII Classification	Class I, active, non-sterile, non-measuring medical device.
Classification rule	Rule 13, Annex VIII (see IFD-DES-017, EU Compliance Plan).
7. Conformity Statement	
Statement	The object of this declaration described above is in conformity with the following applicable Union legislation:
Regulation (EU) 2017/745	On medical devices and to the applicable general safety and performance requirements.
Directive 2011/65/EU	Of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), as amended.
8. Common Specifications	
	None applicable.
9. Conformity Assessment	
Procedure	Conformity assessment performed in accordance with Article 52(7) of Regulation (EU) 2017/745. The manufacturer has demonstrated conformity with the applicable General Safety and Performance Requirements of Annex I through the technical documentation established and maintained in accordance with Annexes II and III.
Notified Body	Not applicable for a non-sterile, non-measuring, non-reusable-surgical Class I device.
10. Standards & Technical	
Reference Location	Applicable standards and technical specifications are identified and maintained within the controlled technical documentation, including IFD-DES-027, EU MDR Annex I Checklist.
11. Additional Information	
	None applicable.
12. Signature	
Place of issue	7018 AC Skinner Parkway, STE270, Jacksonville, Florida 32256 USA
Date of issue (MM/DD/YYYY)	8/11/2026
Name and function	Jon Dekar, Chief Executive Officer
For and on behalf of	DESĪN LLC
Signature