

CERTIFICATE OF MDR NOTIFICATION

Reference No.: MG 0568-2024

Date: 21/10/2024

Order No.: EU AM 0362-2024

This is to certify that, according to the Regulation (EU) 2017/745 we, here at Obelis s.a., have performed all notification duties and responsibilities as the European Authorized Representative (EC REP) of:

Name: Cure Bionics

Address: Rue Abderrahman Ibn Abi Bakr, 231
4023, Sousse
Tunisia

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED REGULATION:

The manufacturer declares that the Class I device(s) comply(ies) with the Regulation including all general safety and performance requirements.

The manufacturer has provided Obelis s.a. with all the appropriate declarations as per the Regulation (EU) 2017/745 Article 52 requirements, including the EC Declaration of Conformity (according to Annex IV), confirming that their Class I medical device(s), as stipulated here below, is/are fulfilling the applicable requirements of the Regulation (EU) 2017/745.

The notification of the following medical device(s) has been completed by Obelis s.a. (EC REP) in compliance with the Regulation (EU) 2017/745 on the 14/10/2024

MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (1 Device 1 Page)

As of the 15/10/2024, and provided that the manufacturer will continue complying with the hereabove mentioned requirements*, he therefore:

- Is required to affix the CE marking on this(ese) device(s);
- May place this(ese) device(s) on the European Union and EEA territory.



Obelis s.a. - O.E.A.R.C.

Registered Address:
Bld Général Wakis 53
1030 Bruxelles
Tel: +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa



Obelis European Authorized Representative Center is member of the European Association of Authorized Representatives (E.A.A.R.).
Obelis s.a. is ISO 9001:2015 and ISO 13485:2016 certified.

*This certificate will become void automatically upon termination of the EAR agreement or removal of the products from EARMandate

Order No.: EU AM 0362-2024
Ref No.: MG 0568-2024

Annex A - List of Devices							
(REGULATION (EU) 2017/745 on medical devices)							
#	Catalogue reference number	Commercial Name	Short description and intended use	EMDN Code	BASIC UDI-DI	Class and Rule under MDR	
1.	ULBPD-V1	Hannibal hand	Bionic prosthetic hand Sophisticated medical prosthesis designed to replace a missing or impaired anatomical function, such as the hand or arm. Equipped with EMG sensors and control mechanisms, it provides the user with precise functionality and control over their movements.	P090499	6192331500015VA	Class I Rule 13	

Obelis s.a.

Date: 21/10/2024

Stamp:

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03