REA MI 1595884
C.F./P.I. 12898410159
Cap. Soc. € 4.000.000

To: **BIONER, S.A.**
C/ ESPIGOLERA 9
08960 SANT JUST DESVERN (BARCELONA)
Spain

and

To whom it may concern:

Your ref.: -
Our ref.: FP-6071/23-nc10
Date: 2023/12/15

**Confirmation letter**

IMQ S.p.A. (Notified Body no. 0051) confirms that the application for MDR certification lodged by the Manufacturer: **BIONER, S.A. (SRN: ES-MF-000004352)**

according to: **Annex IX (I and III) of Regulation (EU) 2017/745**

for the following device(s):

- **"Dental Implants"** as listed in "TD-IM v14_Annex 1.0 Reference list"
- **"Abutments and prosthetic components for implantology"** as listed in "Annex 1.00 TF-PC v12", "Annex 1.0 TF-MU v12", "Annex 1.0 TF-CT v11".

has been accepted by this Notified body.

The MDR certification contract (no. 1001C02644417C) has been signed on 2023/05/10 in accordance with MDR Annex VII, 4.3.

The related conformity assessment procedure is ongoing, and it is as follows:

- technical documentation evaluation (in progress at today's date)
- certification audit (to be carried out after the positive outcome of the technical documentation)
- final review and final decision.

This procedure is expected to be completed within 2025/10/11.

This Notified Body will inform the manufacturer's competent authority about major safety-related shortcomings identified during MDR conformity assessment.

Yours sincerely,

IMQ S.p.A.

Product Conformity
Assessment B.U. – Director

(Eng. Flavio Giorgi)