



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

Respectable  
**ARDET DENTAL & MEDICAL DEVICES SRL**  
VIA LARGA 8  
20122 MILANO (MI)  
and  
To whom it may concern

Your. ref.: -  
Our. ref.: FP-4835/23-nc10  
Milan, 02/10/2023

Subject: letter confirming acceptance of MDR application

IMQ S.p.A. (Notified Body n. 0051) confirms that the application for MDR presented by the Manufacturer: ARDET DENTAL & MEDICAL DEVICES SRL (SRN: IT-MF-000029716) according to: Annex IX (I and III) of (EU) Regulation 2017/745

for the following devices:

- Orix HF Plus
- Orix HF Advantage
- Orix 70 New Edition
- Orix 70 New Edition DG

has been accepted by this Notified Body.

The MDR certification contract (no. 1020C02780757C) was signed on 19/09/2023 in accordance with MDR annex VII, 4.3.

The relevant conformity assessment includes:

- evaluation of the technical documentation (currently underway)
- certification audit (to be carried out after the positive outcome of the technical documentation)
- final review and final decision.

Best regards,

IMQ S.p.A.  
Medical Devices Technical Manager  
Product Conformity Assessment B.U.

(B. Venturelli)

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