

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate No 003/MDR

On the basis of the assessment carried out according to the Annex IX chapter I of the Regulation (EU) n. 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: 3DIEMME SRL

22063 CANTU' (CO) - VIA RISORGIMENTO 9 (ITA) - Italy

for the following devices:

Diagnostic imaging and prosthetic modelling software for dental and maxillo-facial field

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) n. 2017/745 related to medical devices.

First issue date: 2021-01-12

Expiry Date: 2026-01-11

Giorgi Fulvio IMQ

Pag. 2 of/di 4