



EC CERTIFICATE

Certificate No 1938/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

3DIEMME SRL

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

manages in the factory of:

22060 FIGINO SERENZA (CO) - VIA DELLE BARAGGETTE 10 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Diagnostic imaging software and prosthetic modelling

Series: 3Diagnosys® Type ref. RealGUIDE®

Trade mark 3DIEMME

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:

DM16-0006092-01; DM19-0042891-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

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IMQ