



EC CERTIFICATE

Certificate No 1327/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:

CATHMEDICAL CARDIOVASCULAR, S.A.

28670 VILLAVICIOSA DE ODON - MADRID - DUERO 37bis loc.15,CC EL BOSQUE (ESP) - Spain

manages in the factory of:

28670 VILLAVICIOSA DE ODON - MADRID - DUERO 37bis loc.15,CC EL BOSQUE (ESP) - Spain

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

Hemofisiodynamic monitor software

Series: 340.500.006 Type ref. PICASSO

Trade mark CATH MED

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:

10AJ00272; DM15A0435722-01; DM16E0626583-01; DM-0041870-01; DM19-0045185-01.

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.

Date: 2010-04-12
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IMQ