EC CERTIFICATE

Certificate No 160/MDD

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:

EUROCOLUMBUS SRL

20143 MILANO (MI) - VIA FILARGO 36 (ITA) - Italy

manages in the factories of:

20143 MILANO (MI) - VIA FILARGO 36 (ITA) - Italy

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

C-arms, radiographic/fluoroscopic units

Type ref. EUROAMPLI; EUROAMPLI ALIEN; EUROAMPLI ALIEN 9; EUROAMPLI ALIEN 12; EUROAMPLI ALIEN 966; EUROAMPLI ALIEN CARDIO; ALIEN E; ALIEN MINI
Trade mark Eurocolumbus

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.

Reference to IMQ files Nos: 10A9800062 ; 10A9900196, 10A9900237; 10AC00019; 10AD00192; 10ED00021; 10AF00008; 10AF00202; 10EK00098; 10AM00060; 10EN00086; DM14G0312745-01

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: 1999-02-23
Updated: 2014-11-13
Substitution Date: 2014-01-14

IMQ

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".
In any case, it does not remain valid after 2019-01-13 (article 11, clause 11 of the Directive).

This is a translation of the Italian text, which prevails in case of doubts

IMQ CSQ
IMQ S.p.A. Società a socio unico I-20138 Milano - Via Quintiliano 43 - tel. 0250731(r.a.) - fax 0250991500 - info@imq.it - www. imq.it
Rea MI 1595884 - Registro Imprese MI 12898410159 - C.F./P.I.: 12898410159 - Capitale sociale 4.000.000 euro.