CERTIFICATE OF CONFORMITY
WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0411408
Order No.: 34225

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the **Annex V** of the aforementioned directive.

Name of the manufacturer:	CA.MI Snc.di Attolini Mario & C.
Device categories:	Surgical Aspirator
Models:	TOBI - REF RE 310100/27
Risk class:	IIa
Provisions:	The audit of the quality system was based on the provisions in Annex V of the EU-Directive 93/42/EEC
Date of initial audit:	2004-02-18/19
Date of the end of the validity:	2009-12-01
Conditions in Annex V:	See sub clause 3.4 and 5.1
Other relevant conditions:	Article 17.2 of the EU-Directive 93/42/EEC
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled for the manufacturer and the relevant subcontractors.

Date of issue: 2004-11-24

Arild Hansgård

Signature: Arild Hansgård
Principal Engineer

Date of verification: 2004-11-24

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor / Principal Engineer

CE 0470

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