

# CERTIFICATE OF ASSESSMENT - EC

## DET NORSKE VERITAS

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Social Affairs.

**Certificate N°.: 2006-OSL-MDD-0050**

*This is to certify that the Quality System for the product group:*

### **MRI Infusion System**

- defined by manufacturer as Class IIb devices -

*Manufactured by*

**ALPA S.r.l.**

Via Zanoli, 23 – 20161 Milano (MI) Italy

**complies with the applicable requirements of the Directive.**

The quality system for these products has been assessed according to the procedure of conformity assessment described in **Article 11.3.a) and Annex II (excl. section 4)**. Identification of the products covered by this certificate is given in the Appendix.

#### **Limitations:**

The manufacturer must inform Det Norske Veritas Certification AS of any plan for significant changes to the quality system. Annual Periodical Audits will be held to verify the validity of this Certificate.

*Høvik, 14 February 2006*

for Det Norske Veritas Certification AS

*Ad Thore Fiksel*

for Line Gangeskar  
Head of section,  
Product and Personnel Certification

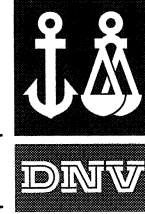
**CE**  
**0434**

*Valid until: 14 February 2011*

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp  
Project engineer

*This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC*



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**APPENDIX**

**Appendix to Certificate No.:** 2006-OSL-MDD-0050

**Manufacturer:** ALPA S.r.l.

**Product group:** MRI Infusion System

The Certificate referred to above covers the following devices:

- **MRidium 3850**
  - **Accessories: REF 1055 ( Infusion Bypass Set ), REF 1056 ( Infusion Set ), REF 1057 (Syringe Adapter Set )**

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14 February 2006

*Cecilie Gudesen Torp*

Cecilie Gudesen Torp

**CE**<sub>0434</sub>