



# 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°.: 2004-OSL-MDD-0093**

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

### **Intra Uterine Devices**

- defined by manufacturer as Class III devices -

*Manufactured by*

### **SMB Corporation of India**

13, 34 – 36, Prem Industrial Estate, Jogeshwari (E), Mumbai – 400 060, India

**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 11.1.a) and Annex II**. 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 substantial changes to the quality system in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.

*Høvik, 10 September 2008*  
for Det Norske Veritas Certification AS

Marianne Spæren  
Head of section  
Product Certification

**CE**  
**0434**

*Valid until: 27 February 2009*  
Original Certificate valid from: 2004-02-27

Jenny Helen Nytn  
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*

# EC design-examination certificate Medical Devices


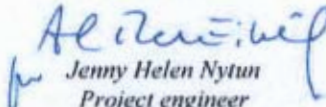


Design Approval no. 2004-OSL-MDD-0093D

<b>Manufacturer name:</b> SMB Corporation of India	
<b>Manufacturer address:</b> 13, 33-36, Prem Industrial Estate, Jogeshwari (E) Mumbai 400 060 India	
<b>Type of medical device and identification no.:</b> Intra Uterine Devices Copper-T Models: 200B, 380A, Cu-375	<b>Class of Medical Device:</b> III
<b>Short description of the medical device:</b> The Copper-T Intra uterine contraceptive device is made of low density Polyethylene wound with copper wire. The "T" is equipped with high-density polyethylene tie thread and contains barium sulphate to render radio-opaque. In the model Copper T 380A, the "T" is also equipped with copper collars. IUD Cu 375 is made of low density polyethylene with two flexible arms with spurs, copper wire is wound around the stem giving a surface area of 375mm <sup>2</sup> with nylon monofilament attached to the stem.	
Sterilisation method: Gamma radiation	
<b>This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.</b>	
<b>Limitations:</b> Any changes in the Design shall immediately be reported to Det Norske Veritas Certification AS in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.	

This certificate is valid until: 2009-02-27

2008-08-10: A new model, in bold, is added to the certificate.

for DET NORSKE VERITAS CERTIFICATION AS  Marianne Spøren Head of section, Product Certification	Høvik, 2008-09-10  for Jenny Helen Nyttun Project engineer
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**APPENDIX**

**Appendix to Certificate No.:** 2004-OSL-MDD-0093  
**Manufacturer:** SMB Corporation of India  
**Product group:** Intra Uterine Devices

The Certificate referred to above covers the following devices:

**2008-09-10; The address is corrected and the following model in bold is added to the certificate:**

- Copper-T
  - Models: 200B, 380A, **Cu-375**

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10 September 2008

  
Jenny Helen Nyttun

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