





EC design-examination certificate

Medical Devices

Design Approval no. 46275-2009-CE-IND-NA

Manufacturer name: SMB Corporation of India	
Manufacturer address: 13, 33-36, Prem Industrial Estate Jogeshwari (E) MUMBAI 400 060 India	
Type of medical device and identification no.: Intra Uterine Devices • CuT 200B, CuT 380A, Cu 375	Class of Medical Device: III
Short description of the medical device: 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 containing barium sulphate with two flexible arms with spurs, copper wire is wound around the stem giving a surface area of 375mm ² with nylon monofilament attached to the stem. Sterilization method: Gamma radiation	
This is to certify that the <i>medical device</i> fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.	
Limitations: 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: 2014-02-27

for DET NORSKE VERITAS CERTIFICATION AS  Marianne Spæren Certification Manager	Høvik, 02 February 2009  Jenny Helen Nyttun Technical Reviewer
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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.