

CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0710416  
Order No.: 94059

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12<sup>th</sup> January 1995 relating to medical devices pursuant to act no. 6 of 12<sup>th</sup> 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 given below:

Name and address of the manufacturer: **SUPREME ENTERPRISES  
D-39, Sector B-3, UPSIDC Tronica City,  
Distt. Ghaziabad – 201102,  
U.P., India**

Device category: Medical Devices

GMDN code: See Appendix 1 to this certificate

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC with the exemption of section 4.

Date of audit: 4<sup>th</sup> & 5<sup>th</sup> September 2007

Date of the end of the validity: 1<sup>st</sup> November 2012

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 by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2007-10-26

Date of verification: 2007-10-26

Signature: Svein Grahnstedt  
MD PhD Senior Lead auditor

Signature: Frank Skarpsno  
Senior Lead Auditor / Principal Engineer

**CE 0470**

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Device category: Medical Devices

**Appendix 1: Page 1 of 1**

The certificate referred to above includes the following devices/models:

Devices	Models		GMDN Codes
<b>SUCTION UNITS:</b>			<b>31789, 32352</b>
<b>Electric</b>	<b>Instavac</b>		
<b>AC / DC</b>	<b>Eterno</b>		
<b>MTP</b>	<b>Vacusafe</b>		
<b>High-Vacum</b>	<b>Accelerator</b>		
<b>Slow</b>	<b>Minic</b>		
<b>Pedal</b>	<b>Supreme</b>		

Date of issue: 2007-10-26

Signature: Svein Grahnstedt

Date of verification: 2007-10-26

Signature: Frank Skarpsno