

CERTIFICATE OF CONFORMITY  
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0801428  
Order No.: 109930

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: **Arizant Healthcare Inc.  
10393 West 70<sup>th</sup> Street  
Eden Prairie, MN 55344  
USA**

Device category: Medical Devices

GMDN code: 41643

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 II of the EC-Directive 93/42/EEC, with the exemption of section 4.

Date of audit: 2006-09-15

Date of the end of the validity: 1<sup>st</sup> February 2013

Nemko EC notification No.: 0470

Remarks: This certificate replaces EU0801428 issued 29<sup>th</sup> January 2008

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: 17<sup>th</sup> July 2008

Date of verification: 17<sup>th</sup> July 2008

Signature: Svein Grahnstedt  
MD PhD Senior Lead Auditor

per   
Signature: Frank Skarpsno  
Senior Lead Auditor / Principal Engineer

**CE 0470**

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**Appendix 1: Page 1 of 1**

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

Device Category	Model	GMDN Code
Irrigation/aspiration unit, surgery, general-purpose	Model 247 Irrigation Warming Unit	41643
	Model 24750 Irrigation Disposable Set	
	Model 24760 Irrigation Disposable Set	
	Model 24765 Irrigation Disposable Set	
	Model 24770 Irrigation Disposable Set	
	Model 24775 Irrigation Disposable Set	
	Model 24780 Irrigation Disposable Set	
	Model 24785 Irrigation Disposable Set	
	Model 24795 Irrigation Patient Line	

Date of issue: 17<sup>th</sup> July 2008

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Signature: Svein Grahnstedt

Per   
Signature: Frank Skarpsno