


REV	DESCRIPTION OF CHANGE	CHANGE REFERENCE	ORIGINATOR	VERIFIED	APPROVED		
C	Updated to IEC 60601-1 2 nd edition 2000	CN-08-072	DATE AND SIGN <i>Esther Parachik</i> 20.06.08 JHA	DATE AND SIGN 20/6-08 <i>Stevanovic</i>	DATE AND SIGN 20/6-08 <i>Self</i>		
B	New DNV certificate	N/A	DATE AND SIGN	DATE AND SIGN	DATE AND SIGN		
A	Release	N/A	DATE AND SIGN 22.03.00 OPR	DATE AND SIGN 22.03.00 MST	DATE AND SIGN 22.03.00 PEC		
THE INFORMATION CONTAINED HEREIN IS PROPRIETARY TO LAERDAL AND SHALL NOT BE USED FOR ANY PURPOSE DETRIMENTAL TO OR BE REPRODUCED WITHOUT PERMISSION OF LAERDAL			DNR <input type="checkbox"/> DHF <input checked="" type="checkbox"/>	 Laerdal helping save lives			
REFERENCE	N/A	REPLACES	N/A	REV	-		
			EU Conformity Declaration LSU				
PRODUCT GROUP	TOOL	PART NO	REV	DOCUMENT NO	PAGE	ATTACH	REV
78	N/A	N/A	-	PRO-R46-0002	1 of 2	0	C

EU-CONFORMITY DECLARATION

It is hereby declared that the "Laerdal **Suction Unit, model 780000, 780010, and 780020**" with accessories, manufactured by Laerdal Medical AS, P.O.Box 377, N-4002 Stavanger, is manufactured in accordance with the product described in the technical file.

Conformity is declared for the essential requirements of Council Directive **93/42/EEC** regarding the harmonization of the membership's laws on **Medical Devices**.

See also certificate number 2005-OSL-MDD-0074 from Det Norske Veritas (id 0434) which is a Notified Body according to article 16 of the Directive.

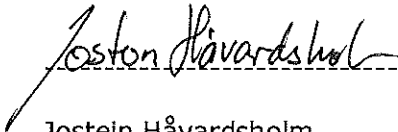
The declaration of conformity is based on the following technical standards:

- **ISO 10079-1:1999 (NS-EN ISO10079-1)**
- **IEC 60601-1 2nd edition 2000**
- **EN 1789 :1999**

-and all referenced standards at a lower level

The product is in risk-class IIa according to rule 11 in appendix IX of the Directive.

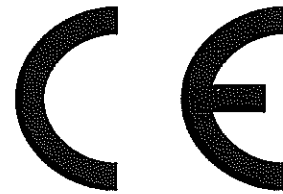
For Laerdal Medical AS



Jostein Håvardsholm,
Technical Product Manager

20/06/2008

Date



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