

Certificate



for European Product Safety

Reference No. 807713

Fetal Heart Monitor

Type designation STAN S31

Certificate holder **Neoventa Medical AB**
Ågatan 32
431 35 Mölndal
SWEDEN

The product complies with the standard(s) EN 60601-1:1990 and A1+A2
EN 60601-1-8:2004 and A1
EN 60601-2-30:2000
EN 60601-2-49:2001

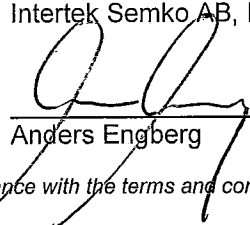
Date of expiry 3 December 2013

Additional information in Appendix.

Certification Body Intertek Semko AB, Product Certification

Place Kista - Stockholm

Signed



Anders Engberg

Date 3 December 2008
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This certificate is issued in accordance with the terms and conditions set out in the Appendix.



Appendix

Reference No. 807713

Technical data

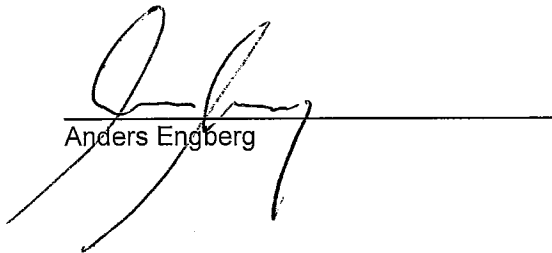
Type designation	STAN S31
Rated voltage (V)	100-240VAC (IEC/EN 60601-1), 100-120VAC (UL 60601-1)
Rated power (VA)	90VA
Frequency (Hz)	50/60Hz
Class	I
Type of protection	Type B on US1/US2 ultrasound transducer and event marker. Type BF on NIBP cuff and SpO2 sensor. Type CF on FECG and TOCO/IUP transducer.
IP-Class	IPX1
Brand name:	STAN®

Manufacturing site(s) Neoventa Medical AB
 Ågatan 32
 431 35 Mölndal
 SWEDEN

Additional information

The product is also in conformity with EN ISO 9919:2005.
Biocompatibility according to EN ISO 10993 has not been evaluated.
Software development according to IEC/EN 60601-1-4 has not been evaluated.

Certification Body Intertek Semko AB, Product Certification Place Kista - Stockholm

Signed  Date 3 December 2008
 Anders Engberg

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