



QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Biogénesis S.R.L
Av. 18 de Julio 1744, Ofs. 1002-1102
11.200 Montevideo, Uruguay

Coverage of Certificate: Design, manufacture and final inspection

Product category: SpO₂-sensors and temperature sensors for
medical applications

Valid until: 4th May 2014

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC.

This Certificate is based on decision no. VTT-C-4052-01-1132-351-09-P0.

Tampere, 4th May 2009


Kaarle Kylmälä




Seppo Lavonen

Certificate no.
VTT-C-4052-01-1132-351-09

Notified Body no. 0537:
VTT Technical Research Centre of Finland
P.O. Box 1300 (Tekniikankatu 1)
FI-33101 TAMPERE
Tel.+358 20 722 111

DECISION

on a quality system and product range covered, based on Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Annex II Section 3.

Decision no.:	VTT-C-4052-01-1132-351-09-P0
Manufacturer:	Biogénesis S.R.L. Av. 18 de Julio 1744, Ofs. 1002-1102 11.200 Montevideo, Uruguay
Date of application:	3.12.2008 / Jorge Villardino
Activity and product category:	Design, manufacture and final inspection of SpO2-sensors and body temperature sensors
Decision:	<p>A certificate will be issued for the manufacturer. The certificate covers the following products:</p> <p>Biogénesis SpO2-sensors, class IIa:</p> <ul style="list-style-type: none"> - Code BIOOX.BC.1 - Code BIOOX.CX.1 - Code BIOOX.CR.1 - Code BIOOX.CR.3 - Code BIOOX.CK.1 - Code BIOOX.CK.3 - Code BIOOX.DS.1 - Code BIOOX.DS.3 - Code BIOOX.DA.1 - Code BIOOX.DA.3 - Code BIOOX.DI.1 - Code BIOOX.DR.1 - Code BIOOX.FD.1 - Code BIOOX.HP.1 - Code BIOOX.HP.3 - Code BIOOX.IR.1 - Code BIOOX.IR.3 - Code BIOOX.KN.1 - Code BIOOX.LM.1 - Code BIOOX.MQ.1 - Code BIOOX.MQ.3 - Code BIOOX.MQ.3.1 - Code BIOOX.MA.3 - Code BIOOX.MD.1

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www.vtt.fi
Business ID 0244679-4

- Code BIOOX.MK.1
- Code BIOOX.ME.1
- Code BIOOX.NC.1
- Code BIOOX.NC.3
- Code BIOOX.NK.1
- Code BIOOX.NK.3
- Code BIOOX.NKN.3
- Code BIOOX.NKT.3
- Code BIOOX.NN.1
- Code BIOOX.NO.3
- Code BIOOX.OH.3
- Code BIOOX.PT.3
- Code BIOOX.PA.1
- Code BIOOX.SI.1
- Code BIOOX.SI.3
- Code BIOOX.SP.1
- Code BIOOX.SP.3
- Code BIOOX.SI.3.1

Biogenesis temperature sensors for medical applications, class IIa:

- Skin sensor, Code BIOTEMP.200P
- Air sensor, Code BIOTEMP.200A
- Skin sensor, Code BIOTEMP.1500P
- Skin sensor, Code BIOTEMP.500P
- Skin sensor, Code BIOTEMP.2000P
- Esophageal – Rectal sensor, Code BIOTEMP.2000R
- Tympanic sensor, Code BIOTEMP.2000T
- Skin sensor, Code BIOTEMP.2001P
- Skin sensor, Code BIOTEMP.900P
- Air sensor, Code BIOTEMP.900A
- Skin sensor, Code BIOTEMP.1000P
- Skin sensor, Code BIOTEMP.600P
- Esophageal – Rectal sensor, Code BIOTEMP.600R
- Tympanic sensor, Code BIOTEMP.600T
- Skin sensor, Code BIOTEMP.700P
- Skin sensor, Code BIOTEMP.400P
- Esophageal – Rectal sensor, Code BIOTEMP.400R
- Tympanic, Code BIOTEMP.400T
- Air sensor, Code BIOTEMP.400A
- Skin sensor, Code BIOTEMP.800P
- Skin sensor, Code BIOTEMP.100P
- Skin sensor, Code BIOTEMP.300P
- Skin sensor, Code BIOTEMP.300A
- Air sensor, Code BIOTEMP.300A
- Skin sensor, Code BIOTEMP.850P




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Justification:	<p>The manufacturer's quality system has been assessed and VTT has found that the quality system and the products meet the requirements of Annex II of Medical Device Directive 93/42/EEC in design, manufacture and final inspection. The decision is based on report no. NB-1132-A1.</p> <p>The company has signed the undertaking to follow the obligations of Annex II of the Directive.</p>
Certificate related to decision:	VTT-C-4052-01-1132-351-09
Valid until:	This decision is valid until 4 th May 2014
Date: 	Tampere, 4th May 2009  Kaarle Kylmä  Seppo Lavonen

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