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DECLARATION OF CONFORMITY To Medical Device Directive 93/42/EEC amended by 2007/47/EC

We: GE Healthcare Finland Oy

declare that the

TruSignal® SpO2 Sensors and Interconnect Cables,

with specified accessories conform to the European Council Directive 93/42/EEC for medical devices as amended by 2007/47/EC.

Classification according to Rule 10 Annex IX (93/42/EEC): IIb

This declaration is based on the Certification of the Full Quality Assurance System, Annex II, Article 3 of the Medical Device Directive, by VTT Expert Services, Notified Body no. 0537.

GMDN Code : 17148, 31658

Date: February 3rd, 2012

Signature: 
Name: Tatja Pasanen
Title: Regulatory Affairs Leader

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GE Healthcare Finland Oy

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Appendix 1
Declaration of Conformity
TruSignal® SpO2 Sensors and Interconnect Cables

TruSignal® SpO2 Sensors and Interconnect Cables:

PRODUCT	ID(model/ code)	GMDN Code
TruSignal® SpO2 Finger Sensor	TS-F-D	17148
TruSignal® SpO2 Finger Sensor, GE connector	TS-F4-GE	17148
TruSignal® SpO2 Finger Sensor, GE connector	TS-F2-GE	17148
TruSignal® SpO2 Finger Sensor, Trusat connector	TS-F4-MC	17148
TruSignal® SpO2 Ear Sensor	TS-E-D	17148
TruSignal® SpO2 Ear Sensor, GE connector	TS-E4-GE	17148
TruSignal® SpO2 Ear Sensor, GE connector	TS-E2-GE	17148
TruSignal® SpO2 Ear Sensor, Trusat connector	TS-E4-MC	17148
TruSignal® SpO2 Wrap Sensor	TS-W-D	17148
TruSignal® SpO2 Sensitive Skin	TS-SE-3	17148
TruSignal® SpO2 FingerTip Sensor	TS-SA-D	17148
TruSignal® SpO2 FingerTip Sensor, GE connector	TS-SA4-GE	17148
TruSignal® SpO2 FingerTip Sensor, Trusat connector	TS-SA3-MC	17148
TruSignal® SpO2 Peditip Sensor	TS-SP-D	17148
TruSignal® SpO2 Peditip Sensor, GE connector	TS-SP3-GE	17148
TruSignal® SpO2 Peditip Sensor, Trusat connector	TS-SP3-MC	17148
TruSignal® SpO2 Interconnect Cable with GE connector	TS-G3	17148
TruSignal® SpO2 Interconnect Cable with Trusat connector	TS-M3	17148
TruSignal® SpO2 Interconnect Cable with Ohmeda connector	TS-H3	17148
TruSignal® SpO2 Interconnect Cable with Nicolay connector	TS-N3	17148
TruSignal® INTEGR H SPO2 FINGER SENSOR	TS-F1-H	17148
TruSignal® INTEGR H SPO2 FINGER SENSOR	TS-F4-H	17148
TruSignal® INTEGR N SPO2 FINGER SENSOR	TS-F4-N	17148
TruSignal® INTEGR SPO2 H EAR SENSOR	TS-E4-H	17148
TruSignal® INTEGR N SPO2 EAR SENSOR	TS-E4-N	17148



Appendix 1
Declaration of Conformity
TruSignal® SpO2 Sensors and Interconnect Cables

TruSignal® INTEGR H SPO2 WRAP SENSOR	TS-W4-H	17148
TruSignal® SpO2 Allfit Sensor	TS-AF-10 TS-AF-25	31658
TruSignal® SpO2 Adult/Pediatric Sensor	TS-AP-10 TS-AP-25	31658

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Atitikties Deklaracija

Pagal direktyvą 93/42 EEB dėl medicinos prietaisų su pakeitimais padarytais 2007/47/EB

Mes: GE Healthcare Finland oy
Pareiškiamo, kad

TruSignal® Sp02 davikliai ir pajungimko kabeliai

Su nurodytais priedais atitinka Europos Tarybos Direktyvą 93/42/EEB dėl medicinos prietaisų su pakeitimais padarytais 2007/47/EB

Klasifikacija pagal taisyklę 10 Priedas IX (93/42/EEB) : IIb

Ši deklaracija yra pagrįsta išsamios kokybės užtikrinimo sistemos , priedas II, straipsnis 3 Medicinos prietaisų Direktyvos, kuri atliko VVT Expert Services, notifikuota įstaiga nr. 0537

GMDN Kodas: 17148, 31658
Data: vasaris 3, 2012 m.

Parašas: /Parašas/
Vardas: Tatja Pasanen
Pareigos: reguliavimo reikalų vadovas

Priedas nr. 1
Atitikties Deklaracija
TruSignal® Sp02 davikliai ir pajungimko kabeliai

TruSignal® Sp02 davikliai ir pajungimko kabeliai

Produktas	ID (modelis/kodas)	GMDN kodas
TruSignal® Sp02 daviklis	TS-F-D	17148
TruSignal® Sp02 daviklis, GE jungtis	TS-F4-GE	17148
TruSignal® Sp02 daviklis, GE jungtis	TS-F2-GE	17148
TruSignal® Sp02 daviklis, Trusat jungtis	TS-F4-MC	17148
TruSignal® Sp02 ausinis daviklis	TS-E-D	17148
TruSignal® Sp02 ausinis daviklis, GE jungtis	TS-E4-GE	17148
TruSignal® Sp02 ausinis daviklis, GE jungtis	TS-E2-GE	17148
TruSignal® Sp02 ausinis daviklis, Trusat jungtis	TS-E4-MC	17148
TruSignal® Sp02 „Ivyniojimo“ (Wrap) daviklis	TS-W-D	17148
TruSignal® Sp02 jautriai odai	TS-SE-3	17148
TruSignal® Sp02 FingerTip daviklis	TS-SA-D	17148
TruSignal® Sp02 FingerTip daviklis, GE jungtis	TS-SA4-GE	17148
TruSignal® Sp02 FingerTip daviklis, Trusat jungtis	TS-SA3-MC	17148
TruSignal® Sp02 PediTip daviklis	TS-SP-D	17148
TruSignal® Sp02 PediTip daviklis, GE jungtis	TS-SP3-GE	17148
TruSignal® Sp02 PediTip daviklis, Trusat jungtis	TS-SP3-MC	17148
TruSignal® Sp02 pajungimo kabelis su GE jungtimi	TS-G3	17148
TruSignal® Sp02 pajungimo kabelis su Trusat jungtimi	TS-M3	17148
TruSignal® Sp02 pajungimo kabelis su Ohmeda jungtimi	TS-H3	17148
TruSignal® Sp02 pajungimo kabelis su Nicolay jungtimi	TS-N3	17148
TruSignal® INTEGR H SP02 „Pirštiniš“ (Finger) daviklis	TS-F1-H	17148
TruSignal® INTEGR H SP02 „Pirštiniš“ (Finger) daviklis	TS-F4-H	17148
TruSignal® INTEGR H SP02 „Pirštiniš“ (Finger) daviklis	TS-F4-N	17148
TruSignal® INTEGR H SP02 „ausinis“ (Ear) daviklis	TS-E4-H	17148
TruSignal® INTEGR H SP02 „ausinis“ (Ear) daviklis	TS-E4-N	17148
TruSignal® INTEGR H SP02 „Ivyniojimo“ (Wrap) daviklis	TS-W4-H	17148
TruSignal® SP02 Allfit daviklis	TS-AF-10 TS-AF-25	31658
TruSignal® SP02 suaugusių/pediatrinis daviklis	TS-AP-10 TS-AP-25	31658