



EC Declaration Of Conformity



Physio-Control, Inc.
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Redmond, WA 98052 USA



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Ann Grove, IDA Business & Technology Park
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Notified Body 0123
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 München, Germany

PHYSIO-CONTROL declares that the CE-marked product

ITEM
LIFEPAK® 1000 Defibrillator
Assembly Battery Replacement Kit
ASSY-BATTERY, PRIMARY, 5/4C CELL,
LIMN02, LP1000

PART NUMBER
See Table 1 and Table 2
See Table 3
See Table 4

Conforms to European Community Council Directive 93/42/EEC (Medical Device Directive), as amended through 2007/47/EC, and is a Class IIb Device assessed under Annex II.

The CE-marked product also conforms to the following EC Directives:

DIRECTIVE

2012/19/EU
2006/66/ EC
2011/65/EU

SUBJECT

Waste Electrical and Electronic Equipment Directive
Battery directive, as amended through 2013/56/EU
Restriction of the use of certain hazardous substances (RoHS Directive)
• Annex I – Category 8 – Medical Devices
• Annex IV – Exemption 17

The CE-marked product complies with the following standards:

STANDARD

EN 1041:2008+A1:2013

EN ISO 15223-1:2012
(Part of EN 1041 TRF)
EN 60601-1:2006+A12:2014
(IEC 60601-1:2012)
EN 60601-1-2:2015
(IEC 60601-1-2:2014)

EN 60601-1-6:2010 +A1:2015
(IEC 60601-1-6:2010+A1:2013)

EN 60601-1-8:2007+A1:2013
(IEC 60601-1-8:2012 A1:2012)

EN 62281:2013
(IEC 62281:2012)
EN 62366:2008 +A1:2015
(IEC 62366:2007+A1:2014)
EN 60601-2-4:2011
(IEC 60601-2-4:2010)

SUBJECT

Information supplied by the manufacturer with medical devices
Symbols to be used with medical device labels, labeling and information to be supplied
Medical electrical equipment. Part 1: General requirements for safety
Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests
Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
General requirements, Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
Safety of primary and secondary lithium cells and batteries during transport
Medical devices – Application of usability engineering to medical devices
Part 2-4: Particular requirements for the safety of cardiac defibrillators

EN 60086-4:2015
(IEC 60086-4:2014)
EN 50419:2006
(Part of WEEE Directive)

EN 62304:2006+A1:2015
(IEC 62304: 2015)

Safety of Lithium Batteries

Marking of electrical and electronic equipment in
accordance with Article 11(2) of Directive 2002/96/EC
(WEEE)

Medical Device Software – Software Life Cycle Processes

The CE-marked product was evaluated with the following accessories:

Power Source
LiMnO₂ primary battery (with discharger)

ECG Accessory
3 wire ECG cable

Separately CE-marked Accessories:

Power Source:
Lithium secondary battery (Lithium Ion)
Battery Charger

Therapy
QUIK-COMBO™ pacing/defibrillation/ECG electrodes
QUIK-COMBO™ RTS pacing/defibrillation/ECG electrodes
QUIK-COMBO™ pacing/defibrillation/ECG electrodes with REDI-
PAK™
Infant/Child reduced energy electrode

Non-Medical Accessories:

Serial communication cable

Table 1

Part Number	Catalog Number	Description	GMDN
320371500476	99425-000138	Arabic, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500477	99425-000139	Arabic, ECG not allowed, Check Circulation voice prompt	48049
320371500478	99425-000134	Croatian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500479	99425-000143	Croatian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500480	99425-000135	Croatian, ECG not allowed, Check Circulation voice prompt	48049
320371500481	99425-000144	Croatian, ECG not allowed, Check Pulse voice prompt	48049
320371500482	99425-000126	Czech, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500483	99425-000127	Czech, ECG not allowed, Check Circulation voice prompt	48049
320371500484	99425-000118	Danish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500485	99425-000119	Danish, ECG not allowed, Check Circulation voice prompt	48049
320371500486	99425-000109	Dutch, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500487	99425-000102	Dutch, ECG not allowed, Check Circulation voice prompt	48049
320371500488	99425-000117	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500489	99425-000142	English Intl, ECG not allowed, Check Pulse voice prompt	48049
320371500490	99425-000113	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
320371500491	99425-000096	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500492	99425-000111	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500493	99425-000094	English Intl, ECG not allowed, Check Circulation voice prompt	48049
320371500494	99425-000112	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
320371500495	99425-000152	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500496	99425-000128	Finnish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500497	99425-000150	Finnish, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500498	99425-000151	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500499	99425-000129	Finnish, ECG not allowed, Check Circulation voice prompt	48049
320371500500	99425-000168	Finnish, ECG not allowed, Check Pulse voice prompt	48049
320371500501	99425-000104	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500502	99425-000097	French, ECG not allowed, Check Circulation voice prompt	48049
320371500503	99425-000162	German, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500504	99425-000105	German, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500505	99425-000098	German, ECG not allowed, Check Circulation voice prompt	48049
320371500506	99425-000147	Greek, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500507	99425-000136	Greek, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500508	99425-000154	Greek, ECG allowed, Check Circulation voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500509	99425-000137	Greek, ECG not allowed, Check Circulation voice prompt	48049
320371500510	99425-000140	Hebrew, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500511	99425-000141	Hebrew, ECG not allowed, Check Circulation voice prompt	48049
320371500512	99425-000124	Hungarian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500513	99425-000125	Hungarian, ECG not allowed, Check Circulation voice prompt	48049
320371500514	99425-000149	I Port, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500515	99425-000120	I Port, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500516	99425-000121	I Port, ECG not allowed, Check Circulation voice prompt	48049
320371500517	99425-000148	I Port, ECG not allowed, Check Pulse voice prompt	48049
320371500518	99425-000107	Italian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500519	99425-000100	Italian, ECG not allowed, Check Circulation voice prompt	48049

Part Number	Catalog Number	Description	GMDN
320371500520	99425-000164	Japanese, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500521	99425-000163	Japanese, ECG not allowed, Check Circulation voice prompt	48049
320371500522	99425-000169	Lithuanian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500523	99425-000170	Lithuanian, ECG not allowed, Check Circulation voice prompt	48049
320371500524	99425-000122	Norwegian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500525	99425-000123	Norwegian, ECG not allowed, Check Circulation voice prompt	48049
320371500526	99425-000110	Polish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500527	99425-000103	Polish, ECG not allowed, Check Circulation voice prompt	48049
320371500528	99425-000157	Russian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500529	99425-000194	Russian, ECG allowed, Check Circulation voice prompt, with ECG off	48049
320371500530	99425-000132	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500531	99425-000133	Russian, ECG not allowed, Check Circulation voice prompt	48049
320371500532	99425-000130	Serbian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500533	99425-000145	Serbian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500534	99425-000131	Serbian, ECG not allowed, Check Circulation voice prompt	48049
320371500535	99425-000146	Serbian, ECG not allowed, Check Pulse voice prompt	48049
320371500536	99425-000158	Slovak, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500537	99425-000159	Slovak, ECG not allowed, Check Circulation voice prompt	48049
320371500538	99425-000155	Slovenian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500539	99425-000160	Slovenian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500540	99425-000156	Slovenian, ECG not allowed, Check Circulation voice prompt	48049
320371500541	99425-000161	Slovenian, ECG not allowed, Check Pulse voice prompt	48049
320371500542	99425-000106	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500543	99425-000099	Spanish, ECG not allowed, Check Circulation voice prompt	48049
320371500544	99425-000153	Spanish, ECG not allowed, Check Pulse voice prompt	48049
320371500545	99425-000108	Swedish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500546	99425-000116	Swedish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500547	99425-000114	Swedish, ECG allowed, Check Pulse voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500548	99425-000101	Swedish, ECG not allowed, Check Circulation voice prompt	48049
320371500549	99425-000115	Swedish, ECG not allowed, Check Pulse voice prompt	48049
320371500550	99425-000171	Romanian, ECG allowed, Check Breathing with ECG on	48049
320371500551	99425-000172	Romanian, ECG not allowed, Check Breathing	48049
320371500552	99425-000177	Persian, ECG allowed, Check Pulse with ECG on	48049
320371500553	99425-000178	Persian, ECG not allowed, Check Pulse	48049
320371500554	99425-000179	Turkish, ECG allowed, Check Circulation with ECG on	48049
320371500555	99425-000180	Turkish, ECG not allowed, Check Circulation	48049
320371500556	99425-000173	Cantonese, ECG allowed, Check Pulse with ECG on	48049
320371500557	99425-000175	Cantonese, ECG not allowed, Check Pulse	48049
320371500558	99425-000174	Mandarin ECG allowed, Check Pulse with ECG on	48049
320371500559	99425-000176	Mandarin, ECG not allowed, Check Pulse	48049
320371500560	99425-000182	Taiwan Mandarin, ECG allowed, Check Pulse with ECG on	48049
320371500561	99425-000183	Taiwan Mandarin, ECG not allowed, Check Pulse	48049
320371500562	99425-000184	Korean, ECG allowed, Check Pulse with ECG on	48049
320371500563	99425-000185	Korean, ECG not allowed, Check Pulse	48049
320371500564	99425-000192	Thai, ECG allowed, Check Pulse with ECG on	48049
320371500565	99425-000187	Thai, ECG not allowed, Check Pulse	48049


Part Number	Catalog Number	Description	GMDN
320371500566	99425-000189	Brazilian, ECG allowed, Check Circulation with ECG on	48049
320371500567	99425-000190	Brazilian, ECG not allowed, Check Circulation	48049
320371500568	99425-000025	English, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500569	99425-000023	English, ECG not allowed, Check Pulse voice prompt	48049
320371500583	99425-000233	Intl English, ECG not allowed, Check Circulation, custom settings for New Zealand	48049

Table 2

Part Number	Catalog Number	Description	GMDN
331706400001	99425-000205	English, ECG allowed, Check Pulse voice prompt, with ECG on	48049
331706400002	99425-000206	English, ECG not allowed, Check Pulse voice prompt	48049
331706400003	99425-000207	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
331706400004	99425-000208	English Intl, ECG not allowed, Check Pulse voice prompt	48049
331706400005	99425-000209	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
331706400006	99425-000210	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400007	99425-000211	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
331706400008	99425-000212	English Intl, ECG not allowed, Check Circulation voice prompt	48049
331706400009	99425-000213	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
331706400010	99425-000214	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400011	99425-000215	French, ECG not allowed, Check Circulation voice prompt	48049
331706400012	99425-000216	Russian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400013	99425-000217	Russian, ECG allowed, Check Circulation voice prompt, with ECG off	48049
331706400014	99425-000218	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
331706400015	99425-000219	Russian, ECG not allowed, Check Circulation voice prompt	48049
331706400016	99425-000220	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400017	99425-000221	Spanish, ECG not allowed, Check Circulation voice prompt	48049
331706400018	99425-000222	Cantonese, ECG allowed, Check Pulse with ECG on	48049
331706400019	99425-000223	Cantonese, ECG not allowed, Check Pulse	48049
331706400020	99425-000224	Brazilian, ECG allowed, Check Circulation with ECG on	48049
331706400021	99425-000225	Brazilian, ECG not allowed, Check Circulation	48049
331706400030	99425-000235	Thai, ECG allowed, Check Pulse with ECG on	48049
331706400031	99425-000236	Thai, ECG not allowed, Check Pulse	48049

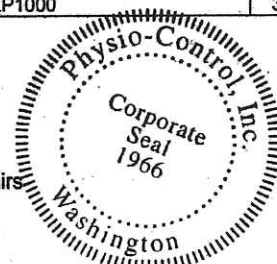
Table 3

Part Number	Catalog Number	Description	GMDN
3206245-004	11141-000100	Assembly Battery Replacement Kit	38558
3205379-006	11141-000156	ASSY-BATTERY,PRIMARY,5/4C CELL,LIMN02,LP1000	38558

Signed June 5, 2020
 Redmond, WA

Caleb L. Simpson

Caleb Simpson
 Director, Regulatory and Clinical Affairs



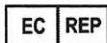
This declaration is issued under the sole responsibility of the manufacturer.

This declaration applies to CE-marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

EC Prohlášení o shodě



Physio-Control, Inc.
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Notifikovaná osoba 0123
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Mnichov, Německo

PHYSIO-CONTROL prohlašuje, že výrobek označený CE

POLOŽKA
LIFEPAK® 1000 Defibrilátor
Montážní výměnná sada baterie
MONTÁŽ-BATERIE, PRIMÁRNÍ, 5/4C
ČLÁNEK, LIMN02, LP1000

ČÍSLA DÍLŮ
Viz Tabulka 1 a Tabulka 2
Viz Tabulka 3
Viz Tabulka 4

Vyhovuje Směrnici Rady Evropského společenství č. 93/42/EEC (Směrnice o zdravotnických prostředcích), ve znění pozdějších úprav dle 2007/47/EC, a je Prostředkem třídy IIb posouzeným podle Dodatku II.

CE-označený výrobek dále vyhovuje níže uvedeným Směrnicím EC:

SMĚRNICE

2012/19/EU
2006/66/EC
2011/65/EU

PŘEDMĚT

Směrnice o odpadovém (waste) elektrickém a elektronickém zařízení
Směrnice pro baterie, ve znění dle 2013/56/EU
Omezení používání jistých nebezpečných látek (Směrnice RoHS)

- Dodatek I - Kategorie 8 - Zdravotnické prostředky
- Dodatek IV - Osvobození 17

CE-označený výrobek vyhovuje níže uvedeným normám:

NORMA

EN 1041:2008+A1:2013
EN ISO 15223-1:2012 (Část EN 1041 TRF)

EN 60601-1:2006+A12:2014
(IEC 60601-1:2012)

EN 60601-1-2:2015
(IEC 60601-1-2:2014)

EN 60601-1-6:2010+A1:2015
(IEC 60601-1-6:2010+A1:2013)

EN 60601-1-8:2007+A1:2013
(IEC 60601-1-8:2012 A1:2012)

EN 62281:2013
(IEC 62281:2012)

EN 62366:2008+A1:2015
(IEC 62366:2007+A1:2014)

EN 60601-2-4:2011
(IEC 60601-2-4:2010)

PŘEDMĚT

Informace dodávané výrobcem se zdravotnickými prostředky
Symboly, které mají být použity u štítků zdravotnických prostředků, označování štítků a informace, které mají být poskytnuty
Zdravotnické elektrické zařízení. Část 1: Všeobecné požadavky na bezpečnost
Zdravotnické elektrické zařízení – Část 1-2: Všeobecné požadavky na bezpečnost – Kolaterální norma: Elektromagnetická kompatibilita – Požadavky a zkoušky
Zdravotnické elektrické zařízení – Část 1-6: Všeobecné požadavky na základní bezpečnost a základní funkční výkonnost — Kolaterální norma: Použitelnost
Všeobecné požadavky, Zkoušky a pokyny pro alarmové systémy ve zdravotnickém elektrickém zařízení a zdravotnických elektrických systémech
Bezpečnost primárních a sekundárních lithiových článků a baterií během přepravy
Zdravotní prostředky – Aplikace inženýringu použitelnosti na zdravotnické prostředky
Část 2-4: Konkrétní požadavky na bezpečnost srdečních defibrilátorů

EN 60086-4:2015
(IEC 60086-4:2014)
EN 50419:2006
(Část Směrnice WEEE)
EN 62304:2006+A1:2015
(IEC 62304: 2015)

Bezpečnost lithiových baterií

Značení elektrického a elektronického zařízení
v souladu s Článkem 11(2) Směrnice 2002/96/EC (WEEE)
Software zdravotnických prostředků - procesy životního cyklu

CE-označený výrobek byl posuzován s následujícím příslušenstvím:

Napájecí zdroj
LiMnO₂ primární baterie (s vybíječkou)

ECG příslušenství
3 žilový ECG kabel

Samostatně CE-označená příslušenství:

Napájecí zdroj:
Lithiová sekundární baterie (Lithiová iontová)
Bateriový nabíječka

Terapie
QUIK-COMBO™ stimulace/defibrilace /ECG elektrody
QUIK-COMBO™ RTS stimulace/ defibrilace /ECG elektrody
QUIK-COMBO™ stimulace/ defibrilace /ECG elektrody s REDIPAK™
Elektroda se sníženou energií pro kojence/děti

Nezdravotnická příslušenství:
Sériový komunikační kabel

Tabulka 1

Číslo dílu	Katalogové číslo	Označení	GMDN
320371500476	99425-000138	Arabic, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500477	99425-000139	Arabic, ECG not allowed, Check Circulation voice prompt	48049
320371500478	99425-000134	Croatian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500479	99425-000143	Croatian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500480	99425-000135	Croatian, ECG not allowed, Check Circulation voice prompt	48049
320371500481	99425-000144	Croatian, ECG not allowed, Check Pulse voice prompt	48049
320371500482	99425-000126	Czech, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500483	99425-000127	Czech, ECG not allowed, Check Circulation voice prompt	48049
320371500484	99425-000118	Danish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500485	99425-000119	Danish, ECG not allowed, Check Circulation voice prompt	48049
320371500486	99425-000109	Dutch, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500487	99425-000102	Dutch, ECG not allowed, Check Circulation voice prompt	48049
320371500488	99425-000117	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500489	99425-000142	English Intl, ECG not allowed, Check Pulse voice prompt	48049
320371500490	99425-000113	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
320371500491	99425-000096	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500492	99425-000111	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500493	99425-000094	English Intl, ECG not allowed, Check Circulation voice prompt	48049
320371500494	99425-000112	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
320371500495	99425-000152	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500496	99425-000128	Finnish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500497	99425-000150	Finnish, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500498	99425-000151	Finnish, ECG allowed, Check Pulse voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500499	99425-000129	Finnish, ECG not allowed, Check Circulation voice prompt	48049
320371500500	99425-000168	Finnish, ECG not allowed, Check Pulse voice prompt	48049
320371500501	99425-000104	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500502	99425-000097	French, ECG not allowed, Check Circulation voice prompt	48049
320371500503	99425-000162	German, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500504	99425-000105	German, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500505	99425-000098	German, ECG not allowed, Check Circulation voice prompt	48049
320371500506	99425-000147	Greek, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500507	99425-000136	Greek, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500508	99425-000154	Greek, ECG allowed, Check Circulation voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500509	99425-000137	Greek, ECG not allowed, Check Circulation voice prompt	48049
320371500510	99425-000140	Hebrew, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500511	99425-000141	Hebrew, ECG not allowed, Check Circulation voice prompt	48049
320371500512	99425-000124	Hungarian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500513	99425-000125	Hungarian, ECG not allowed, Check Circulation voice prompt	48049
320371500514	99425-000149	I Port, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500515	99425-000120	I Port, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500516	99425-000121	I Port, ECG not allowed, Check Circulation voice prompt	48049
320371500517	99425-000148	I Port, ECG not allowed, Check Pulse voice prompt	48049
320371500518	99425-000107	Italian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500519	99425-000100	Italian, ECG not allowed, Check Circulation voice prompt	48049

Číslo dílu	Katalogové číslo	Označení	GMDN
320371500520	99425-000164	Japanese, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500521	99425-000163	Japanese, ECG not allowed, Check Circulation voice prompt	48049
320371500522	99425-000169	Lithuanian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500523	99425-000170	Lithuanian, ECG not allowed, Check Circulation voice prompt	48049
320371500524	99425-000122	Norwegian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500525	99425-000123	Norwegian, ECG not allowed, Check Circulation voice prompt	48049
320371500526	99425-000110	Polish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500527	99425-000103	Polish, ECG not allowed, Check Circulation voice prompt	48049
320371500528	99425-000157	Russian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500529	99425-000194	Russian, ECG allowed, Check Circulation voice prompt, with ECG off	48049
320371500530	99425-000132	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
320371500531	99425-000133	Russian, ECG not allowed, Check Circulation voice prompt	48049
320371500532	99425-000130	Serbian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500533	99425-000145	Serbian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500534	99425-000131	Serbian, ECG not allowed, Check Circulation voice prompt	48049
320371500535	99425-000146	Serbian, ECG not allowed, Check Pulse voice prompt	48049
320371500536	99425-000158	Slovak, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500537	99425-000159	Slovak, ECG not allowed, Check Circulation voice prompt	48049
320371500538	99425-000155	Slovenian, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500539	99425-000160	Slovenian, ECG allowed, Check Pulse voice prompt, with ECG off	48049
320371500540	99425-000156	Slovenian, ECG not allowed, Check Circulation voice prompt	48049
320371500541	99425-000161	Slovenian, ECG not allowed, Check Pulse voice prompt	48049
320371500542	99425-000106	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500543	99425-000099	Spanish, ECG not allowed, Check Circulation voice prompt	48049
320371500544	99425-000153	Spanish, ECG not allowed, Check Pulse voice prompt	48049
320371500545	99425-000108	Swedish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
320371500546	99425-000116	Swedish, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500547	99425-000114	Swedish, ECG allowed, Check Pulse voice prompt, with ECG on, 200/200/360 energy escalation	48049
320371500548	99425-000101	Swedish, ECG not allowed, Check Circulation voice prompt	48049
320371500549	99425-000115	Swedish, ECG not allowed, Check Pulse voice prompt	48049
320371500550	99425-000171	Romanian, ECG allowed, Check Breathing with ECG on	48049
320371500551	99425-000172	Romanian, ECG not allowed, Check Breathing	48049
320371500552	99425-000177	Persian, ECG allowed, Check Pulse with ECG on	48049
320371500553	99425-000178	Persian, ECG not allowed, Check Pulse	48049
320371500554	99425-000179	Turkish, ECG allowed, Check Circulation with ECG on	48049
320371500555	99425-000180	Turkish, ECG not allowed, Check Circulation	48049
320371500556	99425-000173	Cantonese, ECG allowed, Check Pulse with ECG on	48049
320371500557	99425-000175	Cantonese, ECG not allowed, Check Pulse	48049
320371500558	99425-000174	Mandarin ECG allowed, Check Pulse with ECG on	48049
320371500559	99425-000176	Mandarin, ECG not allowed, Check Pulse	48049
320371500560	99425-000182	Taiwan Mandarin, ECG allowed, Check Pulse with ECG on	48049
320371500561	99425-000183	Taiwan Mandarin, ECG not allowed, Check Pulse	48049
320371500562	99425-000184	Korean, ECG allowed, Check Pulse with ECG on	48049
320371500563	99425-000185	Korean, ECG not allowed, Check Pulse	48049
320371500564	99425-000192	Thai, ECG allowed, Check Pulse with ECG on	48049
320371500565	99425-000187	Thai, ECG not allowed, Check Pulse	48049

Číslo dílu	Katalogové číslo	Označení	GMDN
320371500566	99425-000189	Brazilian, ECG allowed, Check Circulation with ECG on	48049
320371500567	99425-000190	Brazilian, ECG not allowed, Check Circulation	48049
320371500568	99425-000025	English, ECG allowed, Check Pulse voice prompt, with ECG on	48049
320371500569	99425-000023	English, ECG not allowed, Check Pulse voice prompt	48049
320371500583	99425-000233	Intl English, ECG not allowed, Check Circulation, custom settings for New Zealand	48049

Tabulka 2

Číslo dílu	Katalogové číslo	Označení	GMDN
331706400001	99425-000205	English, ECG allowed, Check Pulse voice prompt, with EC	48049
331706400002	99425-000206	English, ECG not allowed, Check Pulse voice prompt	48049
331706400003	99425-000207	English Intl, ECG allowed, Check Pulse voice prompt, with ECG off	48049
331706400004	99425-000208	English Intl, ECG not allowed, Check Pulse voice prompt	48049
331706400005	99425-000209	English Intl, ECG allowed, Check Circulation voice prompt, with ECG off	48049
331706400006	99425-000210	English Intl, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400007	99425 000211	English Intl, ECG allowed, Check Pulse voice prompt, with ECG on	48049
331706400008	99425-000212	English, ECG not allowed, Check Circulation voice prompt	48049
331706400009	99425-000213	English Intl, ECG not allowed, Check Pulse voice prompt, with 200/200/360 energy escalation	48049
331706400010	99425-000214	French, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400011	99425-000215	French, ECG not allowed, Check Circulation voice prompt	48049
331706400012	99425-000216	Russian, ECG allowed Check Circulation voice prompt, with ECG on	48049
331706400013	99425-000217	Russian, ECG allowed Check Circulation voice prompt, with ECG off	48049
331706400014	99425-000218	Russian, ECG allowed, Check Breathing voice prompt, with ECG on	48049
331706400015	99425-000219	Russian, ECG not allowed, Check Circulation voice prompt	48049
331706400016	99425-000220	Spanish, ECG allowed, Check Circulation voice prompt, with ECG on	48049
331706400017	99425-000221	Spanish, ECG not allowed, Check Circulation voice prompt	48049
331706400018	99425-000222	Cantonese, ECG allowed, Check Pulse with ECG on	48049
331706400019	99425-000223	Cantonese, ECG not allowed, Check Pulse	48049
331706400020	99425-000224	Brazilian, ECG allowed, Check Circulation with ECG on	48049
331706400021	99425-000225	Brazilian, ECG not allowed, Check Circulation	48049
331706400030	99425-000235	Thai, ECG allowed, Check Pulse with ECG on	48049
331706400031	99425-000236	Thai, ECG not allowed, Check Pulse	48049

Tabulka 3

Číslo dílu	Katalogové číslo	Označení	GMDN
3206245-004	11141-000100	Assembly Battery Replacement Kit	38558
3205379-006	11141-000156	ASSY – BATTERY, PRIMARY, 5/4C CELL, LIMN02, LP1000	38558

Podepsáno dne 5. června 2020
Redmond, WA

Caleb Simpson
Ředitel, Regulační a klinické záležitosti



Toto prohlášení je vydáno na základě vlastní odpovědnosti výrobce.
Toto prohlášení se vztahuje na CE-označené prostředky vyrobené po datu vydání tohoto prohlášení a předtím, než je buď nahrazeno jiným prohlášením, nebo je staženo.

TLUMOČNICKÁ DOLOŽKA/ TRANSLATOR'S CLAUSE

Tlumočnický úkon jsem provedl jako tlumočník jmenovaný rozhodnutím předsedy Krajského soudu v Ústí nad Labem ze dne 22. ledna 1993 pod číslem jednacím 1492 pro jazyk anglický, zapsaný v seznamu znalců a tlumočnicků vedeném Krajským soudem v Ústí nad Labem. Stvrzuji, že překlad souhlasí s textem připojené listiny. V překladu jsem provedl tyto opravy:.....

I made the translator's act as a translator appointed by the decision of the Chairman of the Regional Court in Ústí nad Labem dated 22 January 1993 under the file number 1492 for the English Language, registered in the List of Experts and Translators maintained with the Regional Court in Ústí nad Labem. I certify that the translation matches the text of the attached document. Within the translation, I made the following corrections:.....

Tlumočnický úkon je zapsán v tlumočnickém deníku pod pořadovým číslem/The translator's act is recorded in the Translator's Diary under consecutive number:..... *11280 e.j*

Datum/Date:..... *28. 9. 2010*

Mgr. Karel Krejčí
Tlumočnick jazyka anglického/English language translator

Karel Krejčí
.....
podpis tlumočnicka/translator's signature

Otisk tlumočnické pečeti/Print of translator's seal:

