



EC Declaration Of Conformity



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**Physio-Control
Operations
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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	PART NUMBER
<i>Infant/Child Reduced Energy Defibrillation Electrodes</i>	3202380-xxx (Table 1)
<i>Infant/Child Electrode Starter Kit</i>	3202784-xxx (Table 1)

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	SUBJECT
2012/19/EU	Waste Electrical and Electronic Equipment (WEEE Directive, recast)
2011/65/EU	Restriction of the use of certain hazardous substances (RoHS Directive) <ul style="list-style-type: none">• Annex I – Category 8 – Medical Devices

The CE marked product complies with the following standards:

STANDARD	SUBJECT
EN 60601-1:2006 + A11:2011	General requirements for safety for medical electrical equipment
EN 60601-2-4:2011	Safety requirements for cardiac defibrillators
EN1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2012	Symbols to be used with medical device labels, labeling and information to be supplied
EN ISO 10993-1:2009+AC:2010	Biological evaluation of medical devices
EN 50419:2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)

Table 1

Part Number	Description
3202380-006	ELECTASSY-AED INFANTCHILD REDUCED ENERGY-WW
3202784-009	START KIT-I/C ELECTRODE, LANGUAGE SET 1
3202784-010	START KIT-I/C ELECTRODE, LANGUAGE SET 2

Signed June 16, 2015
 Redmond, WA

Paula Lank
Vice President | 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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.