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European Union (EC) Declaration of Conformity

Under sole responsibility, the undersigned hereby certify that the product (s) described hereinafter as Laboratory Equipment is (are) in conformity with the following European Union (EU) Directives:

DIRECTIVE 2014/30/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 26 February 2014 on the harmonisation of the laws of the Member States relating to Electromagnetic Compatibility (EMC)

DIRECTIVE 2006/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

The undersigned declares that the product described in this document meet the Council Directive(s) provisions that apply to them and the CE Mark CE symbol may be affixed.

Element/Component	Description
General Product Name:	Rolyan Splint Bath Strava Splint Bath
Product Description:	Rolyan and Strava Splint Bath is a reservoir made of a thermoset composite material that holds and heats water. The water bath allows for thermoplastic splint sheets to be softened and made pliable to form to the body. The Rolyan and Strava Splint Bath has a custom LCD display for accurate water temperature readings, user-controlled water temperature and time settings, thermoplastic sheet presets, user presets, sanitation cycles and automatic water drainage.
Model Number(s):	Rolyan Splint Bath Model Numbers: 100.500 (Standard) 100.501(Large) Strava Splint Bath Model Numbers: 100.600 (Standard) 100.601 (Large)
GMDN Code(s)	Not Applicable
Legal Manufacturer: (Name on Label)	Strava Solutions LLC, a subsidiary of Kismet Holdings Group 2733 Kanasita Drive Suite #125 Hixson, TN 37343 USA
Variants:	Not Applicable – Not a Medical Device
Intended Use/Indications for Use:	The Rolyan and Strava Splint Bath is intended for use as a reservoir in hospitals, clinics and other medical facilities to heat and soften thermoplastic used in the splinting process. The device is intended for indoor use only.
MD Directive Classification:	Not Applicable – Not a Medical Device
Notified Body:	Not Applicable for Laboratory Equipment

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Element/Component	Description
EU Authorised Representative:	EMERGO by UL Prinsessegracht 20 2514 AP The Hague The Netherlands
RoHS Directive	2011/65/EU
Harmonized Standard(s)	EN 61326-1:2013 EN 55011:2009/A1:2010 IEC 61010-1 IEC 61010-2-010 IEC 61000-4-2 IEC 61000-4-3 IEC 61000-4-4 IEC 61000-4-5 IEC 61000-4-6 IEC 61000-4-8 IEC 61000-4-11

Engineering Representative

Name: Chad Morgan Signature: Date: 5.13.20

Site Quality Representative

Name: Ron Harris Signature: Date: 5-13-20

Regulatory Affairs Representative

Name: Elijah Wreh Signature: Date: 14-May-20