EC DECLARATION OF CONFORMITY

Manufacturer: Lumitex® Medical Devices, Inc.
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Product Name: BiliSoft 2.0 Phototherapy System
GMDN Code: 33791
Model Name: BiliSoft 2.0 Phototherapy System
Model Number: ES1: Small Pad; ES2: Large Pad; ES3: Homecare, Lg; ES4: Homecare, SM ES5: Small Pad, Export; ES6: Large Pad, Export; ES7: Homecare, Large Pad, Export; ES8: Homecare, Small Pad, Export

	Model Name & Model Number			
Language & Plug	**BiliSoft 2.0 with Large Pad**	**BiliSoft 2.0 with Small Pad**	**BiliSoft 2.0 with Large Pad (Home Use Config)**	**BiliSoft 2.0 with Small Pad (Home Use Config)**
English, US Plug	009766	009791	009765	011559
English, UK Plug	009767	009792	N/A	N/A
English, CE Plug	009768	009793	N/A	N/A
French, US Plug	009769	009794	N/A	N/A
Spanish, US Plug	009770	009795	N/A	N/A
English, Australian Plug	009771	N/A	N/A	N/A
French, CE Plug	009772	009796	N/A	N/A
Spanish, CE Plug	009773	009797	N/A	N/A
German, CE Plug	009774	009798	N/A	N/A
Dutch, CE Plug	009775	009799	N/A	N/A
Japanese, US Plug	009776	009800	N/A	N/A
Chinese, CCC Plug	009777	011657	N/A	N/A
Italian, CE Plug	009778	009801	N/A	N/A
Korean, CE Plug	N/A	009802	N/A	N/A
Swedish, CE Plug	009779	N/A	N/A	N/A
Polish, CE Plug	009780	N/A	N/A	N/A
Russian, CE Plug	009781	009803	N/A	N/A
Finnish, CE Plug	009782	009804	N/A	N/A
Danish, Danish Plug	009783	N/A	N/A	N/A
Greek, CE Plug	N/A	009805	N/A	N/A
Turkish, CE Plug	009784	009806	N/A	N/A
Norwegian, CE Plug	009785	N/A	N/A	N/A
English, Indian Plug	009786	N/A	N/A	N/A
English, Philippine Plug	N/A	009807	N/A	N/A
English, South Africa Plug	009787	009808	N/A	N/A
French, Swiss Plug	009788	N/A	N/A	N/A
German, Swiss Plug	009789	N/A	N/A	N/A
Spanish, US Plug for Mexico	N/A	009809	N/A	N/A
Indonesian, CE Plug	009790	009810	N/A	N/A

LUMITEX™

Thereby undersigned acknowledges on behalf of Lumitex® Medical Devices, Inc. that this product, which bears the CE marking, is in compliance with the applicable provisions set forth in the MDD Medical Device Directive 93/42/EEC and compliance with ISO 13485 - Medical Devices.

BiliSoft 2.0 is a Class IIa product per Annex IX, section 3.1 (Rule 9) of MDD 93/42/EEC. This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Regulatory Affairs Representative

05/12/2020
Date

Authorized Representatives Name: Medical Device Safety Service GmbH
Authorized Representatives Address: Schiffgraben 41
D-30175 Hannover, Germany

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