MERIVAARA

CE

DECLARATION OF CONFORMITY

To European Council Directive 93/42/EEC

We

Merivaara Corp.
Puustellintie 2, FI-15150 LAHTI, FINLAND

declare that the

Q-FLOW

Surgical Light System

Product codes: Q-FLOW SOLO 520210, Q-FLOW DUO 320 520220, Q-FLOW DUO 520222, Q-FLOW TRIO 520230, Q-FLOW MOBILE 520211

Consisting of one or more of following lamp heads, optionally equipped with wireless camera: LAMP HEAD Q-FLOW 4 520241, LAMP HEAD Q-FLOW 4i 520242, LAMP HEAD Q-FLOW 4 LCH 520243, LAMP HEAD Q-FLOW 4i LCH 520244, LAMP HEAD Q-FLOW 6 520251, LAMP HEAD Q-FLOW 6i 520252, LAMP HEAD Q-FLOW 6 LCH 520253, LAMP HEAD Q-FLOW 6i LCH 520254

Class I (Annex IX)
GMDN group: 04, GMDN code: 37332

provided with specified accessories conforms to the European Council Directive 93/42/EEC, Medical Device Directive (Annex VII), corresponding Finnish National Law (629/2010) and European Council Directive 2014/53/EU (Radio Equipment Directive).

The product is controlled in accordance with ISO 9001 and ISO 13485 Quality Management Systems and ISO 14001 Environmental Management System, and meets the requirements of following standards

EN 60601-1:	Medical electrical equipment. Part 1: General requirements for safety
EN 60601-1-2:	Collateral Standard: Electromagnetic compatibility - Requirements and tests.
EN 60601-2-41:	Medical electrical equipment. Part 2-41: Particular requirements for the safety of surgical luminaries and luminaries for diagnosis

August 23rd, 2018

Leena Viljo
CEO

Digitally signed by Ceaicovschi Tudor
Date: 2021.11.03 14:19:24 EET
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