Anexa 7

Specificație tehnică completată

Model: Q-flow 4 + Q-Flow 4, Producător: Merivaara Corp, Tara: Finlanda

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Lampa chirurgicala cu 2 sateliti (caracteristici medii) Cod 130240 Descriere Lampă chirurgicală fără umbre destinată pentru iluminare în investigații chirurgicale majore cu fixare pe tavan cu 2 sateliți Parametrul Specificația Caracterisitici tehnice Sistem de iluminare bazat pe tehnologia LED (Light Emitting Diodes) da Numărul de sateliți 2 Temperatura culorii 4,500 ±500 K Reglarea intensității luminei da Indexul de culoare > 95 Dimensiunea cîmpului, cm Diametrul 24-34 cm Adîncimea ≥ 80 cm Distanța de lucru 0.7-1.5 m Nivelul de iluminare la 1 m distanță satelitul nr.1 ≥ 130 000 lux, satelitul nr.2 ≥ 100 000 lux Rotația 270 grade Ajustare pe verticală, cm ≥ 70 Cresterea temperaturii în campul operator <1º C Alimentarea Rețeaua electrică 220V, 50Hz Durata medie de viață a LED-urilor min. 50000 h Mînere detașabile sterilizabile Panou de control integrat în lampa principal Înălţimea podului 3-4 m	Lampa chirurgicala cu 2 sateliti (caracteristici medii) **DA** Cod 130240 Descriere Lampă chirurgicală fără umbre destinată pentru iluminare în investigații chirurgicale majore cu fixare pe tavan cu 2 sateliți **DA** Parametrul Specificația Caracterisitici tehnice Sistem de iluminare bazat pe tehnologia LED (Light Emitting Diodes) **DA** Numărul de sateliți 2 **DA** Temperatura culorii **3700/4,500 /5000 la alegerea utilizatorului DA** Reglarea intensității luminei **DA** Indexul de culoare 98 **DA** Dimensiunea cîmpului, cm Diametrul **200-320 mm DA** Adîncimea **1500 mm** DA Distanța de lucru **0.65-1.7 m DA** Nivelul de iluminare la 1 m distanță satelitul nr.1 **140 000 lux, DA** satelitul nr.2 - **100 000 lux DA** Rotația 270 grade **DA** Ajustare pe verticală, cm 70 **DA** Cresterea temperaturii în campul operator <1º C **DA** Alimentarea Rețeaua electrică 220V, 50Hz **DA** Durata medie de viață a LED-urilor **min.** 60 000 h **DA** Mînere detașabile sterilizabile **DA** Panou de control integrat în lampa principal **DA tip touch screen** Înălţimea podului 3-4 m **DA**

Digitally signed by Ceaicovschi Tudor
Date: 2022.06.16 15:37:30 EEST
Reason: MoldSign Signature
Location: Moldova

MERIVAARA

Q-FLOW

The award-winning surgical light family

Design optimized for OR's air flow

One cause of contamination is uncontrolled air flow in operating rooms. Q-Flow™ is designed for an optimized air flow that allows ventilation to work properly in an operating room. Traditional surgical light heads cause air to rise in the operating area, resulting in increased particle content and an increased infection burden for the patient. Due to the optimally designed Q-Flow™, with a turbulence intensity of only 15.9 %, there is no additional particle burden created in the operating area. In addition, this also improves the working conditions for the surgical team, as it helps to keep the area clean from harmful smoke and gases.

FLUENT - NEW!

Main features:
- Excellent optical performance
- Design optimized for air flow

VISION

Additional features:
- HD camera option
- Green ambilite

INTELLIGENT

Additional features:
- Intueri™ Sterile user interface
- DOC™ Dynamic Obstacle compensation

- Fluent usability
- Easy to clean
- MeriMote and OpenOR compatible

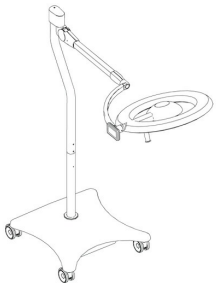
Functional simplicity

- Lightweight

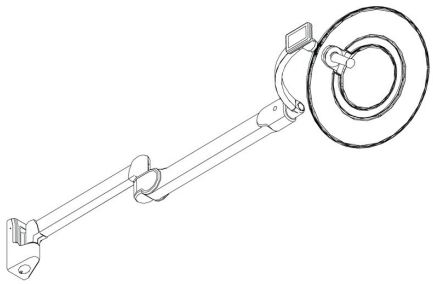
Flexible viewing angles

Maximum comfort and ease of use

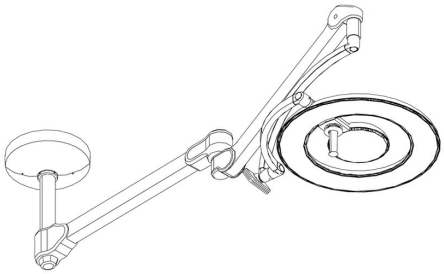
EXAMPLES OF AVAILABLE ARM OPTIONS



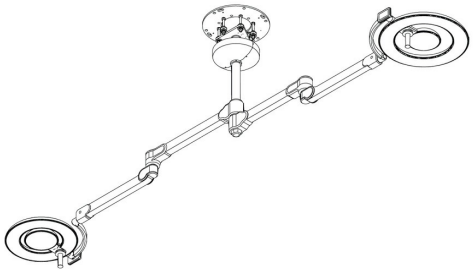
SOLO MOBILE



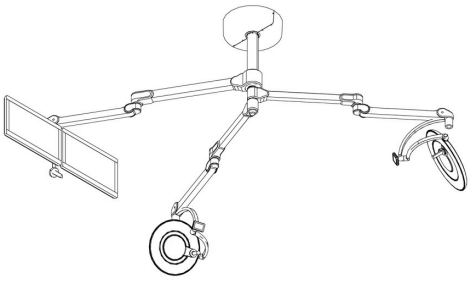
SOLO WALL



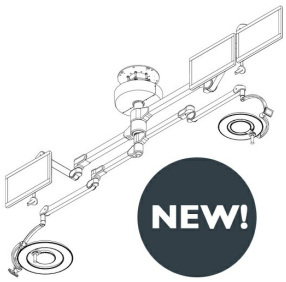
SOLO CEILING
- 50 mm, 65 mm or 110 mm ceiling tube



DUO
- 65 mm or 110 mm ceiling tube

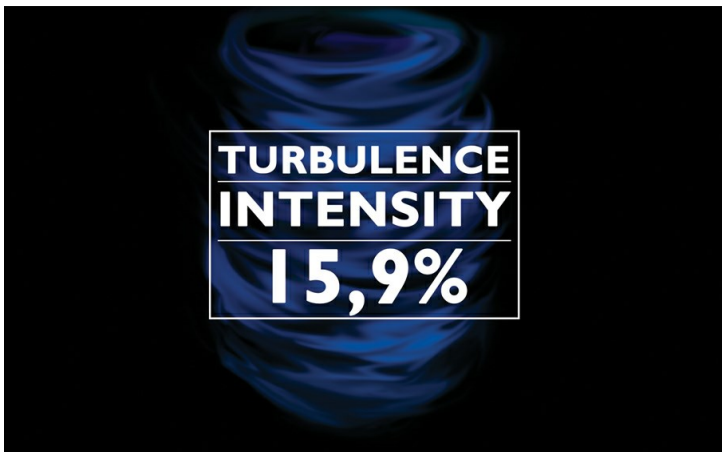


TRIO
- 110 mm ceiling tube



QUAD
- 110 mm ceiling tube

Benefits of the Q-Flow family



REDUCED RISK OF INFECTION

The design of the Q-Flow light is optimized to improve air flow circulation in the operating area. This will help keep the area clean, improving working conditions for the entire surgical team and increasing patient safety. Turbulence intensity is remarkably low 15.9%, when the industry standard specifies it to be below 37.5 %.

PERFECT TISSUE COLOR RENDERING

The R9 value (red) of the Q-Flow light is the best in its class 98, making it perfect for the surgeon to between different tissue and vascular colors. The R13 value (skin) 98 is also excellent, which is particularly important in plastic surgery and in operations where seeing the skin accurately is important.

COMFORTABLE WORKING CONDITIONS

Merivaara's Dynamic Obstacle Compensation (DOC™) decreases the need to adjust the luminaire. Ergonomics and efficiency of the entire surgical team is improved significantly.

- Shadowless light in the surgical area provides optimal light in all circumstances
- Automatic light dimming reduces temperature above surgical team's heads
- Light restores original lighting conditions automatically

INTUITIVE TO USE

Merivaara´s patented Intueri™ system provides surgeons a possibility to adjust the dimming and the field size of the light field from the sterile area, allowing surgeons to keep their focus on the operating area. The Intuitive user interfaces of the Q-Flow touch panel and its auxiliary controllers – multifunctional remote control Merimote™ and integration system OpenOR™ – offer similar, simplified controls for the light and its camera, in multiple languages. This allows users to switch between control devices smoothly as needed.

ERGONOMIC CAMERA SOLUTIONS

The in-light camera unit is completely hidden behind the cover glass, leaving no obstacle in the surgeon´s peripheral view. Thanks to the central position of the camera unit, the camera can always be centered in the operating range. Wireless technology enables the suspension arms rotate a full 360 degrees, allowing surgeons to focus the camera at optimal viewing angle.

reddot award 2017
winner

FENNIAprize 17
GRAND PRIX

REDDOT 2017 WINNER & FENNIA PRIZE 2017 GRAND PRIX WINNER

OpenOR integration system

OpenOR enables you to connect all video and audio sources, medical devices, and room functions to be displayed on monitors or info screens. OpenOR can also control lights, tables, ventilation and blinds, and it communicates with hospital information systems (HIS) and building management systems (BMS).

Video transfer solutions

We can offer complete solutions for transferring live video stream from the Q-Flow lamp camera to other devices in the hospital.

Monitors & Monitor arms

Merivaara offers customized monitor arms for medical monitor mounting.

Display protectors

Provides additional impact protection to your valuable arm mounted medical grade monitors. Optically fully transparent surface reduces glare for optimal image visibility and prevents scratches. Can be removed, cleaned and reapplied. Easy to clean and maintain. Installed at our factory prior to shipment.

Title	Q-Flow 6F	Q-Flow 4F	Q-Flow 6	Q-Flow 4	Q-Flow 6i	Q-Flow 4i
Primary voltage	100 - 240 V	100 - 240 V	100 - 240 V	100 - 240 V	100 - 240 V	100 - 240 V
Secondary voltage	24 V	24 V	24 V	24 V	24 V	24 V
Illumination intensity Ec at 1m distance	160000 lx	140000 lx	160000 lx	140000 lx	160000 lx	140000 lx
Depth of illumination, @ 20%	1800 mm	1500 mm	1800 mm	1500 mm	1800 mm	1500 mm
Depth of illumination, @ 60%	1200 mm	690 mm	1200 mm	690 mm	1200 mm	690 mm
Colour temperature	3700/4400/5100 K	3700/4400/5100 K	3700/4400/5100 K	3700/4400/5100 K	3700/4400/5100 K	3700/4400/5100 K
Light field	200 - 370 mm	200 - 320 mm	200 - 370 mm	200 - 320 mm	200 - 370 mm	200 - 320 mm
Light field diameter, value d10	330 mm	270 mm	330 mm	270 mm	330 mm	270 mm
Light field diameter, value d50	190 mm	150 mm	190 mm	150 mm	190 mm	150 mm
Working distance	700 - 1800 mm	650 - 1700 mm	700 - 1800 mm	650 - 1700 mm	700 - 1800 mm	650 - 1700 mm
Colour rendering index (Ra)	98	98	98	98	98	98
Red colour rendering index (R9)	98	98	98	98	98	98
Number of LEDs	90	69	90	69	90	69
Average life time of LED	>60 000 h	>60 000 h	>60 000 h	>60 000 h	>60 000 h	>60 000 h
Size of light head	700 mm	560 mm	700 mm	560 mm	700 mm	560 mm
Weight of luminaire	16 kg	13 kg	16 kg	13 kg	16 kg	13 kg
Skin colour rendering index (R13)	98	98	98	98	98	98
Integrated dimming (%)	10 - 100 %	10 - 100 %	10 - 100 %	10 - 100 %	10 - 100 %	10 - 100 %
Turbulence intensity, DIN 1946 (%)	15.9 %	35 %	15.9 %	35 %	15.9 %	35 %

Power consumption (W)	100	60	100	60	100	60
Product Code	520210, 520220, 520222, 520230, 5204000	520210, 520220, 520222, 520230, 5204000	520210, 520220, 520222, 520230, 5204000	520210, 520220, 520222, 520230, 5204000	520210, 520220, 520222, 520230, 5204000	520210, 520220, 520222, 520230, 5204000

MERIVAARA

T406117-3

DECLARATION OF CONFORMITY

Following the provisions of Directive 2011/65/EU on electrical and electric equipment.

MANUFACTURER

Merivaara Corporation
Puustellintie 2, FI-15150 Lahti, Finland

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

PRODUCT NAME	**PRODUCT CODE**
Merimote	100060860, 100060970
Practico	145000
Promerix	1000600000
OpenOR	200041001
Q-Flow	520210, 520222, 520230, 520211, 5204000 (optionally equipped with wireless camera)

The products of the declaration described above are in conformity of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 including amending directive 2015/863/EU on the Restriction of the use of certain Hazardous Substances (RoHS) in electrical and electronic equipment.

Conformity is declared based on harmonized standard:

STANDARD	
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

Date: 21.01.2022
Place: Lahti, Finland

Juha Taimisto
CEO, Merivaara Corporation

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
66582-2009-AQ-FIN-FINAS

Initial certification date:
13 May 1998

Valid:
01 January 2022 – 31 December 2024

This is to certify that the management system of

Merivaara Corp.

Puustellintie 2, 15150 Lahti, Finland

has been found to conform to the Quality Management System standard:

ISO 9001:2015

This certificate is valid for the following scope:

Design, development, manufacture, distribution, installation and service of medical devices including operating room integration systems, surgical light systems, operating tables and accessories.

Place and date:
Espoo, 02 November 2021

For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.
ACCREDITED UNIT: DNV Business Assurance Finland Oy Ab, Keilaranta 1, 02150 Espoo, Finland - TEL: +358 10 292 4200. www.dnv.fi/assurance

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
10000503411-MSC-FINAS-FIN

Initial certification date:
13 May 1998

Valid:
01 January 2022 – 31 December 2024

This is to certify that the management system of

Merivaara Corp.

Puustellintie 2, 15150 Lahti, Finland

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Design, development, manufacture, distribution, installation and service of medical devices including operating room integration systems, surgical light systems, operating tables and accessories.

Place and date:
Espoo, 02 November 2021

For the issuing office:
DNV - Business Assurance
Keilaranta 1, 02150 Espoo, Finland

Kimmo Haarala
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

MERIVAARA

T406083-3

DECLARATION OF CONFORMITY

Following the provisions of the Regulation (EU) 2017/745 on medical devices.

CE

MANUFACTURER	**Merivaara Corporation** Puustellintie 2, FI-15150 Lahti, Finland
SRN	FI-MF-000001175

This declaration of conformity is issued under the sole responsibility of Merivaara Corporation

PRODUCT NAME	Q-Flow
PRODUCT CODE	Surgical light systems: Q-FLOW SOLO 520210, Q-FLOW DUO 520222, Q-FLOW TRIO 520230, Q-FLOW QUAD 5204000, Q-FLOW MOBILE 520211 Consisting of following light head options: Q-FLOW 4 520241, Q-FLOW 4i 520242, Q-FLOW 4 LCH 520243, Q-FLOW 4i LCH 520244, Q-FLOW 4F 520246, Q-FLOW 4F LCH 520245 Q-FLOW 6 520251, Q-FLOW 6i 520252, Q-FLOW 6 LCH 520253, Q-FLOW 6i LCH 520254, Q-FLOW 6F 520256, Q-FLOW 6F LCH 520255
CLASS	I
BASIC UDI-DI	643843520RA
EMDN CODE	Z12010701: Fixed scialytic lamps
GMDN CODE	37332, Operating room light system
CONFORMITY ASSESSMENT	Annex II, Annex III, Annex IV
INTENDED USE	The Q-Flow surgical lighting system contains modern operating room luminaires for use in hospitals and health care centres. The luminaires are suitable for use during examinations and surgical operations with high illumination requirements. The HD camera is intended for transferring the image and helping the operation room personnel to follow up surgeries. The camera is not intended for diagnostic use.

Product is in conformity with the applicable provisions to the Regulation (EU) 2017/745, Medical Device Regulation (MDR) and Directive 2014/53/EU, Radio Equipment Directive (RED) of the European Parliament and of the Council. Conformity of the product is supported by meeting the ISO 9001 Quality Management Systems, ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes, ISO 14001 Environmental Management System requirements and ISO 14971 Medical devices - Application of risk management to medical devices.

Product meets the following standards:

STANDARD	
IEC 60601-1:2005+A1:2012	General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010+A1:2013	Collateral standard: Usability
IEC 60601-2-41:2009+A1:2013	Particular requirements for the basic safety and essential performance of surgical luminaries and luminaries for diagnosis
IEC 62366-1:2007+1:2014	Application of usability engineering to medical devices

Date: 13.04.2022
Place: Lahti, Finland

Juha Tahmisto
CEO, Merivaara Corporation