



EU Quality Management Certificate



This is to certify that the company

Ondal Medical Systems GmbH

Wellastraße 6
36088 Hünfeld
Germany

SRN: DE-MF-000000203

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745 Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3. Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	001464 MDR2017Q
Certificate ID	1000169456
Effective date	2024-06-27
Expiry date	2028-02-22
Frankfurt am Main,	2024-06-27



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)



Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-00000203
Certificate ID: 1000169456

Device categories and variants covered by this certificate:

Device category: **MDA 0316 - Medical gas supply systems and parts thereof**
Product name: Ceiling Unit M20 w/MediBoom
Ceiling Unit M20 w/MediLift
Ceiling Unit M20 w/VALIA X
Risk classification: IIb
Basic-UDI-DI: 4061591000790S9
Intended purpose:

- The Ceiling Unit M20 is a medical supply unit, it is intended for:
 - use in the operating theatre, in intensive care and in the medical environment.
 - carrying and easy positioning of medical equipment in the room.
 - the passage and withdrawal of medical gases, vacuum and compressed air, as well as electricity and data.
 - the supply of medical equipment with the aforementioned media, in particular but not exclusively anaesthesia equipment, heart-lung machines, respirators or endoscopic and surgical equipment trolleys
 - the indirect illumination of the working environment by means of an LED light (optional)
- The product is suitable for continuous operation.

Device category: **MDA 0316 - Medical gas supply systems and parts thereof**
Product name: MediSpace
Risk classification: IIb
Basic-UDI-DI: 4061591000462RM
Intended purpose:

- The MediSpace is a medical supply unit, it is intended for:
 - use in the operating theatre, in intensive care and in the medical environment.
 - the passage and withdrawal of medical gases, vacuum and compressed air, as well as electricity and data.
 - the supply of medical equipment with the aforementioned media, in particular but not exclusively anaesthesia equipment, heart-lung machines, respirators or endoscopic and surgical equipment trolleys.
 - the indirect illumination of the working environment by means of an LED light (optional).
- The product is suitable for continuous operation.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000000203
Certificate ID: 1000169456

Device category: **MDA 0316 - Medical gas supply systems and parts thereof**
Product name: Service Head M6
Risk classification: I Ib
Basic-UDI-DI: 4061591000431RA
Intended purpose:

- The Service Head M6 is a medical supply unit, it is intended for:
 - use in the operating theatre, in intensive care and in the medical environment.
 - carrying and easy positioning of medical equipment in the room.
 - the passage and withdrawal of medical gases, vacuum and compressed air, as well as electricity and data.
 - the supply of medical equipment with the aforementioned media, in particular but not exclusively anaesthesia equipment, heart-lung machines, respirators or endoscopic and surgical equipment trolleys.
 - the indirect illumination of the working environment by means of an LED light (optional).
- The product is suitable for continuous operation.

Examinations and tests performed:

001464_A211266MED_02 dated 2023-01-27

001464_A211266MED_03 dated 2023-01-27

Further conditions for or limitations to the validity of the certificate:

n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-02-23	170781759	Change of Certificate Template & Change to the name of the product from "with" to the initial "w/"