



# EU Technical Documentation Assessment Certificate



This is to certify that the company

## Ondal Medical Systems GmbH

Wellastraße 6  
36088 Hünfeld  
Germany

SRN: DE-MF-000000203

has established and maintains the required Technical Documentation in accordance with

### **Annex IX, Chapter II 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 Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

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

Certificate registration no.	001464 MDR2017B
Certificate ID	1000146432
Effective date	2023-11-15
Expiry date	2028-02-22
Frankfurt am Main,	2023-11-15



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 Technical Documentation Assessment Certificate**  
**SRN of Manufacturer: DE-MF-00000203**  
**Certificate ID: 1000146432**

**Device categories and variants covered by this certificate:**

Device category: **MDA 0316 - Medical gas supply systems and parts thereof**  
Product name: Medical Supply Unit  
Models: Ceiling Unit M20 with MediBoom  
Ceiling Unit M20 with MediLift  
Ceiling Unit M20 with 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: Medical Supply Unit  
Models: 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.

Device category: **MDA 0316 - Medical gas supply systems and parts thereof**  
Product name: Medical Supply Unit  
Models: Service Head M6  
Risk classification: IIb  
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.



## Annex to EU Technical Documentation Assessment Certificate

SRN of Manufacturer: DE-MF-000000203

Certificate ID: 1000146432

### Examinations and tests performed:

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	170781757	Addition Ceiling Unit M20