



EU Quality Management Certificate



This is to certify that the company

ALPRO MEDICAL GMBH

Mooswiesenstr. 9
78112 St. Georgen
Germany

SRN: DE-MF-000010603

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.	550742 MDR2017Q
Certificate ID	1000264177
Effective date	2025-09-18
Expiry date	2030-08-06
Frankfurt am Main,	2025-09-18



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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 the certification can only be verified by the QR-code.



Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000010603
Certificate ID: 1000264177

Device categories and variants covered by this certificate:

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: MinutenWipes
Risk classification: IIa
Basic-UDI-DI: ++E251000140006Y
Intended purpose: Alcoholic wet wipes for the quick disinfection and cleaning of surfaces of medical devices.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: MinutenSpray-classic
- KDM KWIPES-SPRAY
- NomoSept
Risk classification: IIa
Basic-UDI-DI: ++E2510001410075
Intended purpose: Alcoholic ready-to-use solution for the quick disinfection and cleaning of surfaces of medical devices.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: WL-cid
- n.cid
Risk classification: IIb
Basic-UDI-DI: ++E251000149008D
Intended purpose: Ready-to-use solution for the disinfection (internal and external surfaces) of medical and dental hollow instruments.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: AlproZyme
Risk classification: IIa
Basic-UDI-DI: ++E251000301006X
Intended purpose: Alkaline-enzymatic granulate for the pre-cleaning during the reprocessing of medical and dental instruments, rotating precision instruments and endoscopes.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: Alprojet-D
- KDM BioKlair Diario
Risk classification: IIa
Basic-UDI-DI: ++E251000508008Q
Intended purpose: Liquid concentrate for the daily disinfection and cleaning of dental suction systems with and without amalgam separator.



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Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: AlproJet-DD
- amalsuc
- bepro suction CD
Risk classification: IIa
Basic-UDI-DI: ++E251000509008V
Intended purpose: Liquid concentrate for the daily disinfection and cleaning of dental suction systems with and without amalgam separator.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: Aspi-Jet
Risk classification: IIa
Basic-UDI-DI: ++E251000718009M
Intended purpose: Liquid concentrate for the disinfection and cleaning of medical suction systems.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: BIB forte eco
- DC Evo
- KDM Biodes-K Forte Eco
- Muliti-Sept
- Multisteril CD
Risk classification: IIa
Basic-UDI-DI: ++E25100093900AW
Intended purpose: Liquid concentrate for the disinfection and non protein-fixing cleaning of medical and dental instruments, rotating precision instruments and endoscopes.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: PlastiSept eco
Risk classification: IIa
Basic-UDI-DI: ++E25100095800B7
Intended purpose: Alcohol-free ready-to-use solution for the disinfection and cleaning of sensitive surfaces of non-invasive medical devices.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: PlastiSept eco Wipes
- Care-Wipes
Risk classification: IIa
Basic-UDI-DI: ++E25100095900BC
Intended purpose: Alcohol-free wet wipes for the disinfection and cleaning of sensitive surfaces of non-invasive medical devices.



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Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: DesNet +
Risk classification: IIa
Basic-UDI-DI: ++E251001008007E
Intended purpose: Liquid concentrate for the disinfection and cleaning of surfaces of non-invasive medical devices.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: Dentosept
Risk classification: IIa
Basic-UDI-DI: ++E251001026007J
Intended purpose: Dentosept® is used to maintain the quality of the procedural water and for the disinfection of procedural waterlines in Dentsply Sirona dental units.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: AlproSan
Risk classification: IIa
Basic-UDI-DI: ++E251001080007W
Intended purpose: Liquid concentrate to maintain the quality of the procedural water and for the disinfection of procedural waterlines in dental units.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: Bilpron
- b.clean
- BioFinndent
- BONAQUA SOLVENT
- Planmeca PlanPure
- RiTron
Risk classification: IIa
Basic-UDI-DI: ++E251002001006Q
Intended purpose: Ready-to-use solution for the disinfection of medical and dental unit waterlines and for the prevention of biofilm formation.



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Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: NIGHT CLEANER
Risk classification: IIa
Basic-UDI-DI: ++E251002001016S
Intended purpose: NIGHT CLEANER is used to disinfect and prevent biofilm formation in the waterlines of all AIRFLOW® Prophylaxis Master and AIRFLOW® One units.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: Alpron
- KDM Pure-Fluid
- RiTren
Risk classification: IIa
Basic-UDI-DI: ++E251002103007D
Intended purpose: Liquid concentrate to maintain the quality of the procedural water and for the disinfection of procedural waterlines in dental units.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: BC-San 100
Risk classification: IIa
Basic-UDI-DI: ++E251002111007A
Intended purpose: Solution for the disinfection and reprocessing of wipe dispenser boxes and pressure bottles (1 - 1.5 L) of independent process water supply systems such as the ALPRO-BCS (BottleCareSystem).

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: PrintoSept-ID
- Dentaclean Abdruckdesinfektion
- KDM Impression-Clean
Risk classification: IIa
Basic-UDI-DI: ++E251006060009H
Intended purpose: Ready-to-use solution for the disinfection and cleaning of dental impressions, worn dental prostheses and dental works.

Device category: **MDN 1211 - Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name: EC-55
Risk classification: IIa
Basic-UDI-DI: ++E251006070009Q
Intended purpose: Liquid concentrate for the disinfection and non protein-fixing cleaning of medical and dental instruments, rotating precision instruments and endoscopes.



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Examinations and tests performed:

550742_A214889MED_01 dated 2024-09-23

550742_A215004MED_02 „WL-cid, n.cid“ dated 2025-07-30

550742_A215005MED_03 „Alprojet-D, KDM BioKlair Diario“ dated 2025-06-18

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	2025-08-07	1000264177	Addition of further product under the devices category MDN 1211