



EU Quality Management Certificate



This is to certify that the company

ALPRO MEDICAL GMBH

Mooswiesenstr. 9
78112 St. Georgen
Deutschland

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	1000321867
Effective date	2026-09-24
Expiry date	2030-08-06
Frankfurt am Main,	2026-09-24



DQS Medizinprodukte GmbH

Sven Hoffmann
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: 1000321867

Class IIb device groups covered by this certificate according to Article 52:

Device group:	EMDN D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Risk classification:	IIb
Intended purpose:	Ready-to-use solution for the disinfection (internal and external surfaces) of medical and dental hollow instruments.

Class IIa, Is, Im, Ir device groups covered by this certificate according to Article 52:

Device group:	EMDN D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Risk classification:	IIa
Device group:	EMDN D0299 - BIGUANIDES FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Risk classification:	IIa
Device group:	EMDN D0599 - OXYGEN PRODUCERS FOR DISINFECTION OF MEDICAL DEVICES - OTHER
Risk classification:	IIa
Device group:	EMDN D0801 - ENZYMATIC DETERGENTS FOR MEDICAL DEVICES
Risk classification:	IIa
Device group:	EMDN D030101- HYPOCHLORITE FOR THE DISINFECTION OF MEDICAL DEVICES
Risk classification:	IIa
Device group:	EMDN D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Risk classification:	IIa

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
550742_A219475MED_04 dated 2026-08-25

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

n/a

Reference to previous certificates:

Version	Date of Issue	Certificate-ID	Description of change
01	2025-08-07	1000178271	Addition of further product under the devices category MDN 1211
02	2025-09-18	1000264177	Summary of Product Groups by EMDN Code