

CERTIFICATE



Management system as per
PN-EN ISO 13485:2016-04

Medical devices – Quality management systems – Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

**"Arkona" Trade Science Grzegorz Kalbarczyk Spółka Jawna
wraz ze spółką zależną**

ARKONA LABORATORIUM FARMAKOLOGII STOMATOLOGICZNEJ GRZEGORZ KALBARCZYK

Nasutów 99C, PL / 21-025 Niemce

with the locations / sites according to the annex

applies a management system in line with the above standard for the following scope

**Design, production, placing on the market and contract manufacturing
of medical devices in the form of liquid products intended for the use in the ear, nose, throat.**

Certificate Registration No. **AC090 MD/0027/5967/2025**

Audit Report No. PL5967_MD/2025

Valid from **16-06-2025**

Valid until **15-06-2028**

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 16-06-2025

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

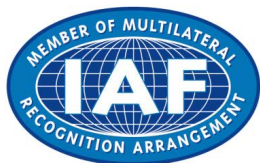
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TÜV NORD Polska Sp. z o.o.

ul. Mickiewicza 29

40-085 Katowice

www.tuv-nord.pl



AC 090

ANNEX

to Certificate Registration No.: **AC090 MD/0027/5967/2025**

issued on 16-06-2025

**"Arkona" Trade Science Grzegorz Kalbarczyk Spółka Jawna
wraz ze spółką zależną
ARKONA LABORATORIUM FARMAKOLOGII STOMATOLOGICZNEJ GRZEGORZ KALBARCZYK
Nasutów 99C, PL / 21-025 Niemce**

Certificate Registration No.	Location	Scope
AC090 MD/0027/5967/2025-000	"Arkona" Trade Science Grzegorz Kalbarczyk Spółka Jawna Nasutów 99C, PL / 21-025 Niemce	Registration address Internal processes within the scope of certification.
	- "Arkona" Trade Science Grzegorz Kalbarczyk Spółka Jawna Łuszczów II 107A i 107AA, PL / 20-258 Wólka	Design, production, placing on the market and contract manufacturing of medical devices in the form of liquid products intended for the use in the ear, nose, throat.
AC090 MD/0027/5967/2025-000	ARKONA LABORATORIUM FARMAKOLOGII STOMATOLOGICZNEJ GRZEGORZ KALBARCZYK Nasutów 99C, PL / 21-025 Niemce	Registration address Internal processes within the scope of certification.
	- ARKONA LABORATORIUM FARMAKOLOGII STOMATOLOGICZNEJ GRZEGORZ KALBARCZYK Łuszczów II 107A i 107AA, PL / 20-258 Wólka	Design, production, placing on the market and contract manufacturing of medical devices in the form of liquid products intended for the use in the ear, nose, throat.

End of the List

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 16-06-2025

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