

Certificate PL18/0859.02

The management system of

ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

Łuszczów II (107A), 20-258 Łuszczów II, Wólka, PL
Registration address: Nasutów 99C, 21-025 Niemce, PL

has been assessed and certified as meeting the requirements of

ISO 13485:2016 ISO EN 13485:2016

For the following activities

Design, manufacturing and sales of liquid medical devices for internal and external use, in the form of sprays, drops, syrups, mouthwashes, oral/nasal/throat moisturizers, ear wax softeners and rectal enemas.

Projektowanie, produkcja i sprzedaż płynnych wyrobów medycznych do użytku zewnętrznego i wewnętrznego, w formie spray, kropli, syropów, płynów do płukania jamy ustnej, płynów nawilżających jamę nosową, jamę ustną oraz gardło, płynów zmiękczejących woskowinę uszną oraz wlewek doodbytniczych.

This certificate is valid from 23 November 2021 until 14 November 2024 and remains valid subject to satisfactory surveillance audits.

Issue 2.

Multiple certificates have been issued for this scope, the main certificate is numbered PL18/0859.00

The validity of this certificate depends on the validity of the main certificate

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