

SGS

Certificate PL18/0859.02

The management system of

ARKONA Laboratorium Farmakologii Stomatologicznej Grzegorz Kalbarczyk

Registration address: Nasutów 99c, 21-025 Niemce, Poland
Production plant: Łuszczów II (107A), Łuszczów II, 20-258 Wólka, Poland

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 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 zmiękczających woskowinę uszną oraz wlewk doodbytniczych.

This certificate is valid from 6 November 2019 until 14 November 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 October 2021

Issue 1. Certified since 6 November 2019

Multiple certificates have been issued for this scope

The main certificate is numbered PL18/0859.00

Authorised by



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