



ТОВ «УКРМЕДСЕРТ»

CERTIFICATE

of conformity with requirements of Technical Regulation
on Medical Devices

Registration Date:

May 20, 2021

№ UA.MD.360-21

Expiry Date: May 19, 2026

This certificate certifies that the application of the full quality assurance system at the stages of design, manufacture and final inspection of medical devices:

Medical diagnostic and therapeutic apparatus

(see one pages annex)

class IIa

manufacturer:

SCIENTIFIC COMPANY KOLIBRI LLC

at the address: **8A, Kinnyi bystreet, Kharkiv, 61001, Ukraine**

meets the requirements of the Technical Regulation on Medical Devices,

approved by the Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No. 753. The conformity assessment procedure was conducted in accordance with Annex 3 «Full quality assurance system» (excluding items 8-11 «Examination of the medical device design»).

Control of compliance of medical devices with the requirements of the specified Technical Regulation is carried out by supervision, the frequency and procedures of which are regulated by the procedures of the conformity assessment body.

The certificate was issued by the Conformity Assessment Body of «UKRMEDSERT» LTD, accredited by the National Accreditation Agency of Ukraine, certificate dated 22.03.2021 № 10240, assigned to the Ministry of Economic Development of Ukraine, under identification number UA.TR.099, address: 1-A Drahomanova str., office 2, Kyiv, 02059 Ukraine, tel.: + 38-044-355-02-30, <https://ukrmedcert.org.ua>

on the basis of the decision of the «UKRMEDCERT» LTD dated 20.05.2021 № 479.

Director



I. Khoteniuk



The validity of a certificate of compliance can be verified in the online Register <https://ukrmedcert.org.ua>

та за тел. +38-044-355-02-30

№	Product name
1.	Non-invasive Hemogram Analyzer AMP
2.	Automatic Noninvasive Express Screening Analyzer ANESA
3.	Medical device for diagnostics DIAMEDSCAN
4.	Diagnostic Aid Device and Non-Invasive Analyzer DAD-ANI
5.	Non-invasive Hemogram Analyzer AMP-PC
6.	Automatic Non-invasive Express Screening Analyzer AMP Model-19
7.	Non-invasive Hemogram Analyzer AMP Model-19
8.	Diagnostic Aid Device and Non-Invasive Analyzer DAD-ANI Model-19
9.	Shock wave therapy device «StarDevice»
10.	Shock wave therapy device «StarDevice PC»
11.	Low Intensity VHF-UHF Therapy Apparatus «BIOL»
12.	KOLIBRI personal screening system

End of list

Director



I.Khoteniuk