



S/N: 001761

Verification of Conformity

No.: **ICR Polska/VC/QC210602**

Name and address of Applicant

ATLANTIC BIO MEDICAL PRIVATE LIMITED
101 BUSINESS POINT 349, WESTERN EXPRESS HIGHWAY, ANDHERI EAST,
MUMBAI 400 069, MAHARASHTRA, INDIA

Name and address of manufacturer:

ATLANTIC BIO MEDICAL PRIVATE LIMITED
KHASARA NO. 230 J.KUANAWALA, DEHRADUN 248 001, UTTARAKHAND INDIA

Product name:

RENACLEAN+ DIALYZER REPROCESSING SYSTEM

Product types:

DIALYZER REPROCESSING SYSTEM

Product trademark:

ATLANTIC

This document confirms that the product sample meets the requirements of the following standards:

- Related with Directives 93/42/EEC and 2014/35/EU:
EN 60601-1:2006+A1:2013

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant. Evaluation has been carried out in accordance with:

Test report:

ERTL(S)/R7035
ERTL(S)/R6670

Tests conducted by:

ELECTRONICS REGIONAL TEST LABORATORY (SOUTH)

Issue date:

26.07.2021

Expiration date:

25.07.2026

Remarks

This Verification of conformity refers to the above mentioned product and its conformity in regards of above mentioned standard(s) was proven on test sample.

This Verification of conformity was issued on voluntary basis and does not imply meeting all essential requirements, assessment of the series-production or any other restricted Notified Bodies conformity assessment procedure appropriate for the product.



marking remarks:

mark is not sanctioned by the following verification of conformity mark given here as reference, can be only use by the manufacturer after applying all essential requirements from relevant directives

document status can be checked: <https://cert.icrpolska.com/>



Director: Rafal Kalinowski

Warsaw, 26.07.2021

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Edition: 4.1.1.D of 18.01.2021

Declaration of Conformity

Name and Address of the manufacturer:

Head Office: ATLANTIC BIO MEDICAL PRIVATE LIMITED
101 BUSINESS POINT 349, WESTERN EXPRESS HIGHWAY,
ANDHERI EAST, MUMBAI 400 069

Works ATLANTIC BIO MEDICAL PRIVATE LIMITED
KHASARA NO. 230 J.KUANAWALA, DEHRADUN 248 001,
UTTRAKHAND INDIA

Description and Identification of the product:

Model Name /Type RENACLEAN+DIALYZER REPROCESSING SYSTEM
Brand Name ATLANTIC

It is declared hereby that

- This declaration of conformity is issued under the sole responsibility of the manufacturer.
- Product fulfills all relevant requirements including Essential Health and Safety Requirements
- Along with Compliance to aforementioned directive it conforms to following Standards:-

Standard Number	Standard Name
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Notified Body Details:

NB Name and Identification ICR POLSKA SP. Z O.O.
Number **NOTIFIED BODY NUMBER : 2703**
Address PLAC PRZYMIERZA 6, 03-944 WARSZAWA, POLAND

Authorized Signatory

Name/Designation Mr. Varun Vazirani/Director

Date: 26.08.2021

Place: Mumbai

ATLANTIC BIOMEDICAL PVT. LTD.

(A WHO - GMP certified company)

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