WORLDWIDE EXCELLENCE CERTIFICATE

WORLDWIDE EXCELLENCE CERTIFICATE

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746 Annex IX, Chapter I and III

CERTIFICATE No. IVDR-WE-10000130123-0123-EU

This is to certify that

Pars Ideal System Iranian Co.

Registered Site: No. 1, East 12th Alley, Beyhaghi Blvd., Argentina Sq., Tehran, Iran

Operational Unit: No. E33, Rash and Sarvestan Junction, 2nd Phase, Kharazmi Industrial Zone, Tehran, Iran

that the manufacturer has established, documented and implemented a quality management system as described in article 10 (8) of the regulation (EU) 2017/746 on *in Vitro* Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the results of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system is subject to periodical surveillance by WECERT. The surveillance assessment includes an assessment of the technical documentation for the devices or devices concerned on the basis of further representative samples.

For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices Annex IX Chapter II certificate is required.

The validity of this certificate can be verified in the Certificate Online Validation System – Certificate Validator – on www.wecert.net

Certificate Issue Date: *January 13, 2023*
Original Certification Date: *January 13, 2023*
Current Certification Date: *January 13, 2023*
Certificate Expire Date: *January 12, 2028*
Issue Number: *1*

For the Accredited Unit:
WECERT Quality Certificates Issuing Services Co.
Sam Peterson
WECERT Certification Body

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid
This certificate is the property of WECERT Quality Certificates Issuing Services Co. and must be returned on request.

WORLDWIDE EXCELLENCE CERTIFICATE

WORLDWIDE EXCELLENCE CERTIFICATE

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Regulation (EU) 2017/746 Annex IX, Chapter I and III

CERTIFICATE No. IVDR-WE-10000130123-0123-EU

Product Family:

Auto Chemistry Analyzer

Intended Use:

Fully Automated Biochemistry Analyzers measure the concentration of certain proteins, enzymes, electrolytes, metabolites, or even drugs in the provided samples of urine, blood, serum, plasma, or other body fluids. The machine consists of a tray where the samples are loaded to be tested.

Model:

IDEALTEC.400

Risk Classification:

Class A (According to Rule 5)

Standard:

EN 1811-1:2011
EN 13612:2022/AC:2002
EN 1041:2008+A1:2013
ISO 15233-1:2016
IEC 61010-1:2010+AMD1:2016
IEC 61326-1:2012
IEC 61326-2-6:2012

The validity of this certificate can be verified in the Certificate Online Validation System – Certificate Validator – on www.wecert.net

Certificate Issue Date: *January 13, 2023*
Original Certification Date: *January 13, 2023*
Current Certification Date: *January 13, 2023*
Certificate Expire Date: *January 12, 2028*
Issue Number: *1*

For the Accredited Unit:
WECERT Quality Certificates Issuing Services Co.
Sam Peterson
WECERT Certification Body

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid
This certificate is the property of WECERT Quality Certificates Issuing Services Co. and must be returned on request.