



شماره ۰۲۴۱۵۴

ردیف دفتر ثبت



جمهوری اسلامی ایران

تأیید می‌شود - اداره مترجمین رسمی

نیکان رقامی

Official English Translator to the Judiciary

License No. 921

Nikan Raghami



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**OFFICIAL TRANSLATION**

IRI Emblem

Islamic Republic of Iran

Ministry of Health and Medical Education

IFDA Emblem

General Department of Reference Laboratories for Food, Drug, and Medical Equipment Control

Authorized Laboratory, "Research Center of Informatic Industries"

Address: Food and Drug Administration, Corner of Shahid Vahid Nazari St., Fakhr Razi St., Opposite University of Tehran

Entrance Door, Tehran, Iran | Tel: +98(21)61927000 | Fax: +98(21)66176931 | Postal Code: 1314715311

www.fda.gov.ir

QR Code

Laboratory Code: 94242917204

License No.: 5861/4011/1

Date of Issue: 22/10/2022

Valid Until: 22/10/2025

**OPERATION LICENSE**

By virtue of Article 22 of the Bylaw of Establishment and Approval of Authorized Laboratories for Food, Drug, and Medical Equipment Control, Notice No. D/101/1029 dated 01/08/2021, and considering the Technical Committee Statutes No. 79 dated 13/09/2022, by virtue of this license, the Authorized Laboratory, "Research Center of Informatic Industries" located at Piece No. D7, Golgasht St., Golzar St., Fanavari Blvd., Parand Industrial Town, Robat Karim, is authorized to practice within the approved scope of activities. In case of evidence in violation of the above bylaw provisions, and non-approval of the subsequent supervision results, it will be acted pursuant to the respective laws and regulations.

Any change in the contents of the License is subject to obtaining required licenses from Food and Drug Administration.

**Laboratory Particulars:**Title of Laboratory: **Research Center of Informatic Industries**

Type of Laboratory: Authorized Laboratory

Name of Cofounder: Research Center of Informatic Industries Co.

Name of Officer: **AHMAD REZA KELISHADI**

Laboratory Tel: +98(21)56418864

Activity Time: 8:00 to 15:00

Address: Piece No. D7, Golgasht St., Golzar St., Fanavari Blvd., Parand Industrial Town

Scope of Activity: Medical Equipment

Scope of Performance:

|    |                                                                                                                                                                                       |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | IP Tests of Medical Electrical Equipment in accordance with standard IEC 60529                                                                                                        |
| 2  | Medical Electrical Equipment Software Lifecycle Tests in accordance with standard IEC 62304                                                                                           |
| 3  | Medical Electrical Equipment Fire Hazard Tests in accordance with standard IEC 60695-11-10                                                                                            |
| 4  | Medical Electrical Equipment Alarm Systems Tests in accordance with standard IEC 60601-1-8                                                                                            |
| 5  | Medical Electrical Equipment Usability Tests in accordance with standard IEC 60601-1-6                                                                                                |
| 6  | Home Ventilators Particular Tests for Ventilator-Dependent Patients in accordance with standard ISO 80601-2-72                                                                        |
| 7  | Medical Electrical Equipment and Medical Electrical Systems General Tests Intended for Use in the Medical Emergency Services Environment in accordance with standard IEC 60601-1-1-12 |
| 8  | Medical Electrical Equipment and Home Medical Electrical Systems General Tests in accordance with standard IEC 60601-1-1-11                                                           |
| 9  | Laboratory Autoclaves Specific Tests in accordance with standard BS 2646                                                                                                              |
| 10 | Hospital Autoclaves Specific Tests in accordance with standard BS EN 285                                                                                                              |
| 11 | Infant Incubators Specific Tests in accordance with standard IEC 60601-1-2-19                                                                                                         |
| 12 | Laboratory Incubators Specific Tests in accordance with standard DIN EN 12880                                                                                                         |
| 13 | Respiratory Gas Monitors Specific Tests in accordance with standard ISO 80601-2-55                                                                                                    |



نام صاحب سند: مرکز صنایع تحقیقات انفورماتیک - هزینه ترجمه و خدمات دفتری: 8062500 ریال بابت ترجمه قرارداد - تعداد سطر متن قرارداد: 130

آدرس: میدان ونک، ابتدای خیابان ولیعصر، پست مبرقی، پلاک 4، طبقه 4، واحد 404

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|    |                                                                                                                                                                            |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14 | Medical Equipment, In Vitro Diagnostic (IVD) Specific Tests in accordance with standard IEC 61010-2-101                                                                    |
| 15 | Specific Tests for Patient Handling Equipment Used in Road Ambulances in accordance with standard BS EN 1865-1                                                             |
| 16 | Specific Tests for Patient Handling Equipment Used in Road Ambulances in accordance with standard BS EN 1865-2                                                             |
| 17 | Specific Tests for Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring, Cosmetic and Aesthetic Use in accordance with standard IEC 6101-2-57 |
| 18 | Medical Suction Equipment Specific Tests in accordance with standard ISO 10079-1                                                                                           |
| 19 | Medical Suction Equipment Specific Tests in accordance with standard ISO 10079-2                                                                                           |
| 20 | Medical Suction Equipment Specific Tests in accordance with standard ISO 10079-3                                                                                           |
| 21 | Specific Tests for Medical Devices Sterilizing and Disinfecting Equipment in accordance with standard BS 3970-1                                                            |
| 22 | Physiotherapy Equipment Specific Tests in accordance with standard IEC 60601-2-10                                                                                          |
| 23 | Control Equipment Specific Tests in accordance with standard IEC 61010-2-201                                                                                               |
| 24 | Specific Tests for Diagnostic, Therapeutic, Cosmetic, and Surgical Laser Equipment in accordance with standard IEC 60601-2-22                                              |
| 25 | Laser Equipment Specific Tests in accordance with standard IEC 60825-1                                                                                                     |
| 26 | Operating Tables Specific Tests in accordance with standard IEC 60601-2-46                                                                                                 |
| 27 | Medical Beds Specific Tests in accordance with standard IEC 60601-2-52                                                                                                     |
| 28 | Surgical Luminaires Specific Tests in accordance with standard IEC 60601-2-41                                                                                              |
| 29 | Dentistry Operating Lights Specific Tests in accordance with standard ISO 9680                                                                                             |
| 30 | Specific Tests for Optical Fibre Communication Systems in accordance with standard IEC 60825-2                                                                             |
| 31 | Laboratory Centrifuges Specific Tests in accordance with standard IEC 61010-2-020                                                                                          |
| 32 | Specific Tests for Small Portable Steam Sterilizers in accordance with standard EN 13060                                                                                   |
| 33 | Dry Heat (Heated Air) Sterilizers Specific Tests in accordance with standard ANSI/AAMI ST50                                                                                |
| 34 | Medical Materials and Equipment Sterilizers Specific Tests in accordance with standard IEC 61010-2-040                                                                     |
| 35 | Cells and Batteries Specific Tests in accordance with standard IEC 62133-2                                                                                                 |
| 36 | Anesthesia Systems Specific Tests in accordance with standard ISO 80601-2-13                                                                                               |
| 37 | Dentistry Patient Chair Specific Tests in accordance with standard ISO 6875                                                                                                |
| 38 | Infant Physiotherapy Specific Tests in accordance with standard IEC 60601-2-50                                                                                             |
| 39 | Image Projectors Specific Tests in accordance with standard IEC 62471-5                                                                                                    |
| 40 | Infant Radiant Warmers Specific Tests in accordance with standard IEC 60601-2-21                                                                                           |
| 41 | Lamps and Lamp Systems Specific Tests in accordance with standard IEC 62471                                                                                                |
| 42 | Specific Tests for Heating Devices Including Blankets, Pads or Medical Mattresses in accordance with standard IEC 80601-2-35                                               |
| 43 | Specific Tests for Ventilators in Emergency Ward in accordance with standard ISO 80601-2-84                                                                                |
| 44 | Ventilator Specific Tests in accordance with standard BS EN ISO 10651-1                                                                                                    |
| 45 | Ventilator Specific Tests in accordance with standard BS EN ISO 10651-2                                                                                                    |
| 46 | Ventilator Specific Tests in accordance with standard BS EN ISO 10651-3                                                                                                    |
| 47 | Ventilator Specific Tests in accordance with standard BS EN ISO 10651-4                                                                                                    |
| 48 | Ventilator Specific Tests in accordance with standard BS EN ISO 10651-5                                                                                                    |
| 49 | Critical Care Ventilators Specific Tests in accordance with standard ISO 80601-2-12                                                                                        |
| 50 | Dental Units Specific Tests in accordance with standard BS EN ISO 7494-1                                                                                                   |
| 51 | Dental Units Specific Tests in accordance with standard BS EN ISO 7494-2                                                                                                   |
| 52 | Tests for Electromagnetic Compatibility of Medical Electrical Equipment in accordance with standard IEC 60601-1-2                                                          |
| 53 | General Tests for Electrical Equipment for Measurement, Control, and Laboratory Use in accordance with standard IEC 61010-1                                                |



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|    |                                                                                             |
|----|---------------------------------------------------------------------------------------------|
| 54 | Medical Electrical Equipment General Tests in accordance with standard IEC 60601-1          |
| 55 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-1  |
| 56 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-14 |
| 57 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-2  |
| 58 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-27 |
| 59 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-29 |
| 60 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-6  |
| 61 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-64 |
| 62 | Medical Electrical Equipment Environmental Tests in accordance with standard IEC 60068-2-78 |
| 63 | Medical Electrical Equipment Risk Management Tests in accordance with standard ISO 14971    |

Signed: Dr. Mehdi Ansari DoGaheh, Acting-Manager of Reference Laboratories for Food, Drug, and Medical Equipment Control  
Sealed: Reference Laboratories for Food, Drug, and Medical Equipment Control, Food and Drug Administration

Certified to be an accurate translation from the attached certified copy in Persian, Tehran, Iran.

02/11/2024

