2020

Ministry of Health and Social development
Secretariat of the Government of Health
A.N.M.A.T.

ANNEX II

INITIAL DECLARACTION OF CONFORMITY- PM CLASS I- II

Revision number: 00

PM number: 265-36

Product Descriptive Name: Software application

Identification code and technical name UMDNS: 16-560. Digital imaging system, for angiographic / cardiovascular use

Risk Class: Class II

Brand of the medical product (s): CIRCLE CARDIOVASCULAR IMAGING

Models (in case of class II and equipment):

CVI42

Exact percentage-quantitative composition (if applicable): NA

Authorized Indications: the Software application CVI42 is used for images process, allowing visualization, process, and analyze cardiovascular images.

Shelf life (if applicable): 13 months

Sterilization method (if applicable):NA

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Presentation: Unite

Sales Conditions: Exclusive Sale to Healthcare Professionals and Institutions

Manufacturer name: CIRCLE CARDIOVASCULAR IMAGING INC

Manufacturer site: 1100, 800 5th Avenue SW, Calgary, Alberta, T2P 3T6, Canadá

In the name and representation of the firm LEXEL S.R.L., the legal officer and the technical manager declare under oath that the medical products listed in this Annex satisfy the Essential Safety and Efficiency Requirements (RESE) provided for by ANMAT Provision No. 4306/99, which they comply with and is available of the health Authority the technical documentation that contains the requirements requested in Annexes III.B and III.C of the Technical Regulation approved by ANMAT Provision N°. 2318/02 (TO 2004) and ANMAT Provision No. 727/13.

COMPLIANCE WITH R.E.S.E. ANMAT PROVISION No. 4306/99 AND RISK MANAGEMENT

TEST / VALIDATION / RISK MANAGEMENT	LABORATORY / PROTOCOL N °	DATE OF ISSUE
1) EN ISO 13485:2016 EN ISO 14971:2012 US FDA	NA	NA
2) EN ISO 13485:2016 EN ISO 14971:2012 ISO 15223:2012 EN1041:2008 MDD93/42/EEC(M5) US FDA QSR	NA	NA
3)	NA	NA

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Design control requirements in ISO 13485:2016 and US FDA QSR IEC62304:2006 Software Life Cycle Management		
4) EN ISO 13485:2016 EN ISO 14971:2012 MDD 93/42/EEC (M5) US FDA QSR	NA	NA
6) EN ISO 14971:2016 EN ISO 13485:2016	NA	NA
10) EN ISO 13485 IEC 60601-1 ISO 14971 EN 62304	NA	NA
10) Design control requirements in ISO 13485:2016 and US FDA QSR	NA	NA
13.1) ISO 15223:2012 IEC 62604:2006	NA	NA
13.3 y 13.3) ISO 15223:2012	NA	NA
13.4) MDD 93/42/EEC (M5)	NA	NA
14) MDD 93/42/EEC (Including directive 2007/47/EC)	NA	NA

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The legal officer and his technical manager are responsible for the veracity of the documentation and information presented and declare under oath to keep in their establishment and at the disposal of the sanitary authority the documentation declared therein and the one established by Provision 727/13, subject to notice which establishes Law No. 16,463, Decree No. 341/92 and those that correspond to the Criminal Code in case of falsehood.

In case of inaccuracy or falsity of the information or documentation, the National Administration may suspend, cancel, prohibit the commercialization and request withdrawal from the market of what has already been authorized and initiate the summaries that may correspond.

PLACE AND DATE: Argentina, June 22, 2020

anmat
RAVA Nestor Juan
CUIL 20218361677

anmat
GONZALEZ Maria Celeste
CUIL 27136546878

2020

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This DECLARATION OF CONFORMITY has been issued in accordance with the provisions of ANMAT Provision No. 9688/10 being registered in the National Registry of Medical Technology Producers and Products (RPPTM) in favor of LEXEL SRL under the number PM 265-36
The marketing of the products identified in this declaration of conformity authorized in the city of Buenos Aires in 22 of June 2020, which will be valid for 5 years from the date.

Processed by File N °: 1-0047-3110-000866-20-1

anmat
MARCELA CLAUDIA Rizzo
CUIL 27169736184

anmat
MANENTI Mariano Pablo
CUIL 23256388839

Ministry of Health
Secretary of Health Quality
A.N.M.A.T.

ANNEX II

MODIFICATION CONFORMITY DECLARATION – PM CLASS I-II

Revision number: 265-36#0001

Date of Issue of the Revision Declaration 00-Authorizing Provision or its revalidation:
22/06/2020

PM Number:

265-36

Descriptive Product Name:

SOFTWARE APPLICATION

UMDNS Identification Code and Technical Name:

16-560 Digital Imaging Systems, for Angiographic/Cardiovascular Use

Risk Class:
Class II

Brand of medical product(s):

CIRCLE CARDIOVASCULAR IMAGING

Models (in case of class II and equipment):

CVI42

Exact qualitative-quantitative percentage composition (if applicable):

N/A

Authorized indication(s):

The CVI42 Software Application is used for image processing, allowing to view, process and analyze cardiovascular images.

Shelf life period (if applicable):

5 years

Sterilization Method (if applicable):

N/A

Presentation form:

Unitary

Condition of use:

Exclusive use for healthcare professionals and institutions

Manufacturer name:

CIRCLE CARDIOVASCULAR IMAGING INC

Place/s of production: 1800,
707 8th Avenue SW, Calgary, Alberta, T2P 1H5, Canada

On behalf of and representing the firm LEXEL SRL, the legal representative and the technical representative declare under oath that the medical products listed in this Annex satisfy the Essential Safety and Efficacy Requirements (RESE) provided for by ANMAT Provision No. 4306/99, that they comply and that the technical documentation containing the requirements requested in Annexes III.B and III.C of the Technical Regulation approved by ANMAT Provision No. 2318/02 (TO 2004) and ANMAT Provision No. 9688/19 is available to the Health Authority.

COMPLIANCE WITH RESE ANMAT PROVISION No. 4306/99 AND RISK MANAGEMENT

TESTING/VALIDATION/RISK MANAGEMENT	LABORATORY/ N° OF PROTOCOL	DATE OF ISSUE N

1 - EN ISO 13485:2016+A11:2021 MDD/93/42/EEC (M5) USFDA QSR EN ISO 14971:2019+A11:2021 EN 62366- 1:2015+A1:2020	N/A	N/A
2 - EN ISO 13485:2016+A11:2021 MDD 93/42/EEC (M5) USFDA QSR EN ISO 14971:2019+A11:2021 ISO 15223-1:2021	N/A	N/A
3 - Design control requirements in EN ISO 13485:2016+A11:2021 and US FDA QSR EN 62304:2006+A1:2015 Software Life Cycle Management	N/A	N/A
4 - EN ISO 13485:2016+A11:2021 MDD 93/42/EEC (M5) USFDA QSR EN ISO 14971:2019+A11:2021	N/A	N/A
5 - EN ISO 13485:2016+A11:2021 MDD 93/42/EEC (M5) USFDA QSR EN ISO 14971:2019+A11:2021 ISO 15223-1:2021	N/A	N/A
6 - EN ISO 14971:2019+A11:2021 6a -	N/A	N/A
MDD 93/42/EEC (M5) MEDDEV 2.7.1 9.1	N/A	N/A
- MDD 93/42/EEC (M5) EN ISO 14971:2019+A11:2021 10.1	N/A	N/A
and 10.2 - Design control requirements in EN ISO 13485:2016+A11:2021 and US FDA QSR 10.3 -	N/A	N/A
Council Directive 80/181/EEC, as last amended by Directive 89/617/EEC	N/A	N/A
12.1a - Design control requirements in EN ISO 13485:2016+A11:2021 and US FDA QSR EN ISO 14971:2019+A11:2021 EN 62304:2006+A1:2015 IEC 82304-1:2016	N/A	N/A
12.9 y 13.1 - EN 62304:2006+A1:2015 13.2 -	N/A	N/A
ISO 15223-1:2021 13.3 y 13.6	N/A	N/A
- MDD 93/42/EEC (M5)	N/A	N/A

The legal representative and his technical representative are responsible for the veracity of the documentation and information presented and declare under oath to maintain in their establishment and make available to the health authority the documentation declared there and that establishes Provision 9688/19, under penalty of what is established in Law No. 16,463, the Decree No. 341/92 and those corresponding to the Penal Code in case of forgery.
In case of inaccuracy or falsity of the information or documentation, the National Administration may suspend, cancel, prohibit the marketing and request withdrawal from the market of what is already authorized and initiate any relevant investigations.

PLACE AND DATE: Argentina, November 1, 2024

Legal Officer

Firma y Sello
Signature and Seal

RAVA Nestor Juan
CUIL 20218361677

Technical Manager

Firma y Sello
Signature and Seal

GONZALEZ Maria Celeste
CUIL 27136546878

Ministry of Health
Secretary of Health Quality ANMAT

This DECLARATION OF CONFORMITY has been issued in accordance with the provisions of ANMAT Provision No. 9688/19, and the modification was registered in the National Registry of Producers and Medical Technology Products (RPPTM) in favor of LEXEL SRL under number PM 265-36 in the City of Buenos Aires on November 1, 2024. The commercialization of the product(s) identified in this declaration of conformity is authorized,

which will maintain the validity stated in the initial Declaration revision 00 or Authorizing Provision or its revalidation.

TERRIZZANO Maria Lorena
CUIL 23242965604

Registry Evaluation Directorate

Signature and Seal

National Institute of Medical Products

Signature and Seal

Code "N°rev legajo#version" effective from 02/07/22, replaces the previous coding.

The validity of this document must be verified using the QR code.

Processed by File No.: 1-0047-3110-006777-24-5

OCAMPO Sebastian Alejandro
CUIL 20263321732

ABRIOLA Leticia Adriana
CUIL 27323186494