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

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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.

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