ITALCERT S.r.l.
viale Sarca, 336 - IT 20126 MILANO MI
tel. +39 0266104876 - fax +39 0266101479
E- mail italcert@italcert.it

Notified Body n° 0426

ITALCERT

CERTIFICATE N° 104-02-00-DM

(in compliance with Annex V of the Directive 93/42/EEC)

ITALCERT

certifies the

Production Quality Assurance System
applied for the manufacture and final inspection
of "Medical Devices" - MD -
by the manufacturer

BIODIAGRAM S.r.l.

Via Bruno Buozzi, 1 - 80040 SAN SEBASTIANO AL VESUVIO (NA) - ITALY

Digitally signed by Guțan Ghenadie
Date: 2022.09.08 10:04:33 EEST
Reason: MoldSign Signature
Location: Moldova

in the headquarters located in

Località Boscofangone snc
80035 NOLA (NA) - ITALY

complies with the requirements stated in

Directive 93/42/EEC - Annex V

limited to the aspects of manufacture concerned with the conformity of the MD - class I - with the metrological requirements

and authorizes the same manufacturer to mark

CE 0426

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito
MANAGING DIRECTOR

First issue date	Renewal date	Expire date
2009-05-22	2019-06-21	2024-05-21

This certificate must be published only in integral form and accompanied by its Annex 1.
This certificate is the English translation of the certificate n°104-02-00-DM issued by ITALCERT Srl in Italian language.
In case of discrepancy you must refer to the original certificate issued in Italian language.

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Annex 1 to Certificate n° 104-02-00-DM

GRAPH PAPERS FOR DIAGNOSTIC RECORDS
(class I with measuring function)

Graph papers - package	*COD: [P xxx y ααα βββ γγγ]*
Graph papers - roll	*COD: [R xxx y ααα βββ γγγ]*

Milan, 2019-06-21

dr. ing. Roberto Cusolito
Managing Director

Nola, 17th January 2020

BIODIAGRAM SRL
legal office in Via B. Buozzi,
1-80040 San Sebastiano al Vesuvio (Na) Italy,
warehouse in Via Boscofangone - 80035
Nola (NA), Italy

For presentation to the
Agency for Medicines and Medical Devices
of Bosnia and Herzegovina
Banja Luka,
Bosnia and Herzegovina

Ul. Veljka Mlađenovića, bb
78000 Banja Luka
Bosna i Hercegovina

AUTHORIZATION LETTER

We **Biodiagram s.r.l.** with legal office in Via B. Buozzi, 1-80040 San Sebastiano al Vesuvio (Na) Italy and warehouse in Via Boscofangone - 80035 Nola (NA), Italy do hereby authorize **"Medicom" d.o.o. Bijeljina**, Ulica Save Šumanovića, broj 89, 76300 Bijeljina, Bosna i Hercegovina, to register our products on the territory of Bosnia and Herzegovina– as our distributor of all products of our manufacture.

As the manufacturer, we guarantee our products against defects in material or workmanship, and provide services based on the standard terms and conditions of our warranty policy.

This Authorization letter is valid until 31st December 2022.

Date
Signature and stamp

BIODIAGRAM srl
Amministratore Unico
Partita IVA: 035 2490 1218

BIODIAGRAM
CARTE DIAGRAMMATE

SISTEMA DI GESTIONE CERTIFICATO
ITALCERT
UNI EN ISO 9001:2008
UNI CEI EN ISO 13485:2012

EC DECLARATION OF CONFORMITY

ACCORDING TO THE REQUIREMENTS CONTAINED IN 'ANNEX I PROVIDED BY D. LGS. 46/97

AMENDED BY D. LGS. 37/10 - DIRECTIVE RECEPTION 2007/47 / EC, DIRECTIVE CORRECTION 93/42/EC AND REGULATED BY Annex VII OF THIS LAW

The undersigned BIODIAGRAM S.r.l with legal office in Via Bruno Buozzi, 1-80040 San Sebastiano al Vesuvio (NA) and warehouse in Via Boscofangone - 80035 Nola (NA) manufacturer of the medical device called:

CHART PAPERS FOR MEDICAL USE

Code	Description
PXXXXXXXXXXXX/RXXXXXXXXXXXX	**CHART MEDICAL PAPERS, ELECTROCARDIOGRAPHIC RECORDING PAPER**

DECLARES

under its own responsibility that:

- the above device meets all applicable provisions in the above mentioned Directive 2007/47 / EC, Directive correction 93/42 / EEC on Medical Devices
- the medical device is class I* WITH MEASUREMENT FUNCTION, in accordance with Annex IX of Directive 2007/47 / EC, Directive correction 93/42 / EEC;
- for this purpose, a specific CE conformity marking has been issued by the Notified Body no. 0426 with certificate no. 104-02-00-DM
- Biodiagram is committed to preserve and make available to the entities responsible for the dossier Product Technician (FT \ EC \ 02), specified in Appendix V of the Directive Directive 2007/47 / EC, Directive 93/42 / EEC reference to a period of at least five years after the last marketing of the last lot or serial number of specified devices.

It therefore declares that the device concerned is in compliance with the description in Directive 2007/47 / EC, Directive correction 93/42 / EEC implemented in Italy by Legislative Decree no. 46/97 amended with Legislative Decree no. 37 / 10.

The following standards and/or other normative documents:

UNI EN ISO 13485-2012
UNI EN ISO 9001-2008

Nola, 2th September 2020

BIODIAGRAM S.r.l
CEO Domenico Maiello
BIODIAGRAM srl
Amministratore Unico
Partita IVA: 035 2656 1216

BIODIAGRAM s.r.l.
Sede Legale: Via Bruno Buozzi, 1
80040 San Sebastiano Al Vesuvio (NA), Italy
Sede Oper. e Stabilimenti: Via Boscofangone, snc (Zona ASI Nola-Marigliano)
80035 Nola (NA), Italy
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P.IVA/C.F./C.C.I.A.A.: IT 03526561216 - R.E.A.: NA 0608254
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BIODIAGRAM
CARTE DIAGRAMMATE

SISTEMA DI GESTIONE CERTIFICATO
ITALCERT
UNI EN ISO 9001:2008
UNI CEI EN ISO 13485:2012

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AMENDED BY D. LGS. 37/10 - DIRECTIVE RECEPTION 2007/47 / EC, DIRECTIVE CORRECTION 93/42/EC AND REGULATED BY Annex VII OF THIS LAW

The undersigned BIODIAGRAM S.r.l with legal office in Via Bruno Buozzi, 1-80040 San Sebastiano al Vesuvio (NA) and warehouse in Via Boscofangone - 80035 Nola (NA) manufacturer of the medical device called:

CHART PAPERS FOR MEDICAL USE

Code	Description
PXXXXXXXXXXXX/RXXXXXXXXXXXX	**CHART PAPERS FOR MEDICAL USE, ELECTROENCEPHALOGRAPHIC RECORDING PAPER**
SNC-UPPXXXXX	**VIDEOPRINTER PAPER,** **ECHOCARDIOGRAPHIC RECORDING PAPER**

DECLARES

under its own responsibility that:

- the above device meets all applicable provisions in the above mentioned Directive 2007/47 / EC, Directive correction 93/42 / EEC on Medical Devices
- the medical device is class I, in accordance with Annex IX of Directive 2007/47 / EC, Directive correction 93/42 / EEC;
- Biodiagram is committed to preserve and make available to the entities responsible for the dossier Product Technician (FT \ EC \ 02), specified in Appendix V of the Directive Directive 2007/47 / EC, Directive 93/42 / EEC reference to a period of at least five years after the last marketing of the last lot or serial number of specified devices.

It therefore declares that the device concerned is in compliance with the description in Directive 2007/47 / EC, Directive correction 93/42 / EEC implemented in Italy by Legislative Decree no. 46/97 amended with Legislative Decree no. 37 / 10.

The following standards and/or other normative documents:
UNI EN ISO 13485-2012
UNI EN ISO 9001-2008
Nola, 2th September 2020

BIODIAGRAM S.r.l
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BIODIAGRAM
CARTE DIAGRAMMATE

Manufacturer's Statement for
GMDN(Global Medical Device Nomenclature)

Name: Chart medical paper
Description A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG). This is a single-use device.
Code 16754
Our Ref: PXXXXXXXXXXXX/RXXXXXXXXXXXXX
Composition: cellulose paper layer with thermosensitive surface
Definitio: A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG). This is a single-use device.

Name: Echocardiographic recording paper
Description: A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an echocardiograph, typically from a cardiovascular ultrasound imaging system or other device, in the form of measured physiologic parameters as an echocardiogram. This is a single-use device.
Code 16755
Our Ref: SXXXXXXXXXX
Definition: A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an echocardiograph, typically from a cardiovascular ultrasound imaging system or other device, in the form of measured physiologic parameters as an echocardiogram. This is a single-use device.
Composition: extrusion of polyamide 6.0 and 6.6

Name: Chart medical paper for medical Use
Description A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG). This is a single-use device.
Code 16756
Our Ref: PXXXXXXXXXXXX/RXXXXXXXXXXXXX
Definition A device prepared from a thin sheet of fibrous material, typically with preprinted graphics and designed for recording the output of an electrocardiograph (ECG), or other device, in the form of measured physiologic parameters as an electrocardiogram (ECG). This is a single-use device.
Composition: cellulose paper layer with thermosensitive surface

Nola, 29/09/2020

BIODIAGRAM srl
Amministratore Unico
Partita IVA: 035 2656 1216

BIODIAGRAM SRL
Sede Legale: Via B. Buozzi, 1 80040 San Sebastiano al Vesuvio (NA)
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