



DECLARATION OF CONFORMITY

"RECORDING PAPER WITHOUT MEASURING FUNCTION FOR MEDICAL EQUIPMENTS"

to the essential requirements of Enclosure I of Directive 93/42/CEE, as prescribed by Enclosure VII of the a.m. Directive 93/42/CEE.

The company MODUL DIAGRAM S.r.l., having its seat in Castel Bolognese (RA) Italy, via IV Novembre n. 337/347, 48014 - Italy, is the manufacturer of the medical device named "Recording paper without measuring function for medical equipments", and in particular the codes covered in this family are:

UMDNS CODES:

- 16937 Paper, Photographic
- 16754 Paper, Recording, ECG
- 16755 Paper, Recording, Echocardiograph
- 16756 Paper, Recording, EEG
- 16757 Paper, Recording, Other
- 15369 Paper, Recording

declares under its own responsibility that the a.m. medical devices comply with the essential requirements expressed in Annex I of the COUNCIL Directive 93/42/CEE (implemented in Italy by Decree 46/97) related to MEDICAL DEVICES.

To this purpose, the company MODUL DIAGRAM s.r.l. hereby assures and declares under its own responsibility:

1. that the above mentioned device complies with the essential requirements of Enclosure I of the Directive 93/42/CEE;
2. that the above mentioned device must be considered as belonging to Class I, according to what prescribed by the Rule I of Enclosure IX of the a.m. Directive 93/42/CEE;
3. that the above mentioned device IS NOT A MEASURING DEVICE;
4. that the above mentioned device is commercialised in NON STERILE boxes;
5. that the above mentioned device IS NOT BOUND TO CLINIC RESEARCHES;
6. in addition, declares to have set up an evaluation procedure of the acquired experience, according to what prescribed by Enclosure VII, point 4, of the a.m. Directive;
7. the manufacturer commits himself to keep and put to the disposal of the Notified Body the technical documentation specified in Enclosure VIII of the Directive 93/42/CEE, as well as the production and checking records (batch record) for thirteen years from the last manufacturing date of the product,
8. that the device complies with the requirements of the following laws:
 - EN 980: Graphical symbols for use in the labelling of medical devices;
 - EN 780: Packaging – Pictorial marking for handling of goods;
 - EN 1041: Terminology, symbols and information provided with medical devices - Information supplied by the manufacturer with medical devices;
 - EN 10993: Biological evaluation of medical devices.
9. that the above mentioned device complies with the requirements of the Directive 93/42/CEE, is manufactured and commercialised with first date of introduction 15/12/97 and CE brand according with the Article 17 of the Directive 93/42/CEE and as indicated in the technical sheet of the product, in the application of a company's quality system found compliant with the UNI EN ISO 9001:2008 by Certiquality, Via Giardino 4, - 20123 Milano (Italy): Certificate No. 2139 (first issuing date 20.04.1999).

The manufacturer furthermore declares to apply and maintain a suitable procedure which grants the application of the post-marketing surveillance procedure required by the a.m. Directive 93/42/CEE.

Attachments:

- List of product codes and products description of the medical bearing the CE mark;
- Copy of the Certificate 2139 - Certiquality.
- Copy of the Certificate IT-6698 – IQNET International Certification Network.

The manufacturer
modul diagram s.r.l.
The Legal Representative
Domenico Scardovi



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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
00026	175789/R	Z1302	10830TRN12	630451	Z1302	5712TRN8	630670	Z1302
00031	630127	Z1302	10925TRN12	1619115	Z1302	5715TRN8	1242651	Z1302
00034	630128	Z1302	110100TRN12	190088/R	Z1302	5715I12	630135	Z1302
00035	630129	Z1302	11010TRN12	1619116	Z1302	5715TRN12	152416	Z1302
00036	630131	Z1302	11011TRN8	190098/R	Z1302	5720TRN12	1220787	Z1302
00037	175791/R	Z1302	11012TRN12	630507	Z1302	5725TRN12	626191	Z1302
00040	630108	Z1302	11018VP1	633977	Z1302	5730TRN12	626194	Z1302
00042	630109	Z1302	11020TRN12	630527	Z1302	5740TRN12	376013/R	Z1302
00043	630110	Z1302	11020VP1	143434	Z1302	5750TRN12	626195	Z1302
00044	630111	Z1302	11020VP2	633978	Z1302	575TRN8	1619111	Z1302
00045	175794	Z1302	11025TRN12	630528	Z1302	5815TRN12	626243	Z1302
00046	630090	Z1302	11030TRN12	630529	Z1302	58250TRN12	1619110	Z1302
00049	630091	Z1302	11050TRN12	630531	Z1302	5825TRN12	626245	Z1302
00052	630092	Z1302	11210TRN12	165100/R	Z1302	5860TRN12	1619109	Z1302
00053	630093	Z1302	11211TRN8	1573794	Z1302	6025TRN12	152419/R	Z1302
00054	630094	Z1302	11213TRN12	1619117	Z1302	6025TRN20	190104/R	Z1302
00055	175803/R	Z1302	112122TRN12	630331	Z1302	6030I12	630136	Z1302
00059	630067	Z1302	11215TRN12	630327	Z1302	6030TRN12	626205	Z1302
00061	630068	Z1302	11225TRN12	630328	Z1302	6030TRN16	630629	Z1302
00062	630069	Z1302	11230TRN12	630329	Z1302	6045TRN20	630627	Z1302
00065	630070	Z1302	11235TRN12	630330	Z1302	6050TRN12	626206	Z1302
00066	175804/R	Z1302	11425TRN12	190093/R	Z1302	6060TRN12	626230	Z1302
00068	630061	Z1302	11430TRN12	630307	Z1302	6225TRN12	152439	Z1302
00074	630062	Z1302	11525TRN12	630308	Z1302	6230TRN12	630352	Z1302
01251	630064	Z1302	12030TRN12	630309	Z1302	6250TRN12	630353	Z1302
01257	360065	Z1302	12530TRN12	630310	Z1302	6320TRN12	410824/R	Z1302
01270	175807/R	Z1302	14040TRN16	190101	Z1302	6330TRN12	630354	Z1302
01273	630055	Z1302	21525TRN12	367496/R	Z1302	6330TRN16	630630	Z1302
01736	630056	Z1302	30100020	1484668	Z1302	6950TRN12	630355	Z1302
01757	630057	Z1302	30100221	1484671	Z1302	7025TRN12	152441	Z1302
01768	630058	Z1302	373TRN8	630667	Z1302	7030TRN12	630347	Z1302
02268	175809/R	Z1302	374TRN8	630668	Z1302	7130TRN12	630348	Z1302
02290	630047	Z1302	377TRN11	190102/R	Z1302	7225TRN12	630349	Z1302
02291	834629	Z1302	4525TRN12	105469/R	Z1302	7525TRN12	630350	Z1302
02518	630048	Z1302	5025TRN12	1307978	Z1302	7925TRN12	175631	Z1302
02570	630049	Z1302	5025TRN16	1619113	Z1302	7930TRN12	630358	Z1302
02649	630050	Z1302	5030TRN12	626236	Z1302	7930TRN16	630631	Z1302
10530TRN12	190080/R	Z1302	5525I12	175640	Z1302	7940TRN12	630360	Z1302
106.031	1619160	Z1302	5530TRN12	626239	Z1302	7950TRN12	630361	Z1302
10740TRN12	630447	Z1302	57100TRN12	626197	Z1302	8015TRN11	630628	Z1302
10820TRN12	630448	Z1302	5710TRN12	1619112	Z1302	8015TRN12	1484670	Z1302
10825TRN12	630450	Z1302	5710TRN8	630669	Z1302	8020TRN8	630671	Z1302

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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
8025TRN12	175627	Z1302	FUD216280P1	193752/R	Z1302	NI216280P3	630377	Z1302
8025TRN12	175327/R	Z1302	FUD216300P	630707	Z1302	NK110100P	193924	Z1302
8030TRN12	630297	Z1302	FUD216300P1	630435	Z1302	NK110140P	629987	Z1302
8825TRN12	630298	Z1302	FUD216300PA1	630434	Z1302	NK110140P1	1619234	Z1302
8850I12	630137	Z1302	FUD5075P1	630727	Z1302	NK110150P	629988	Z1302
9030TRN12	175625	Z1302	FUD63100P	630729	Z1302	NK110150P1	629991	Z1302
9525TRN12	630027	Z1302	FUD63100P1	630730	Z1302	NK110150P2	629992	Z1302
9850I12	630138	Z1302	FUS4425	193768/R	Z1302	NK150100P	629993	Z1302
AN161120P	199371/R	Z1302	GEY110120P	199226/R	Z1302	NK210140P	629994	Z1302
AS125150P	193695/R	Z1302	GR5750	193777/R	Z1302	NK210295P1	193939/R	Z1302
AS216280P	630607	Z1302	HE105100P	193788/R	Z1302	NK210300P	193972/R	Z1302
AS216280P1	630608	Z1302	HE110140P	1464524	Z1302	NK210300P1	630687	Z1302
AV100/250	193702/R	Z1302	HE207280P	630428	Z1302	NK300300P	630688	Z1302
AV100/250/	630587	Z1302	HE220300P	630430	Z1302	NK50100P2	630689	Z1302
BCR5020	1459508	Z1302	HE50100P	630431	Z1302	OB161120P	193975/R	Z1302
BR215280P2	210285/R	Z1302	HM215100	193800	Z1302	OB210150P	630295	Z1302
BT112125P	1619209	Z1302	HM21630	630415	Z1302	OB210150P2	630296	Z1302
BT112125P1	1619210	Z1302	HM21650	410827/R	Z1302	OB210150P3	194556/R	Z1302
BTL210150PA2	1406665	Z1302	HM21660	630416	Z1302	OB210150P3A1	629287	Z1302
CGA11025	193707/R	Z1302	HNE151150P	193824/R	Z1302	OB210300P	629288	Z1302
CGA12623/1	630567	Z1302	HP120150P1	193829/R	Z1302	OB216300P1A1	629289	Z1302
CGA13425	630568	Z1302	HP210300P	1527730	Z1302	OB216300P1A2	1501149	Z1302
CGAPRE	630569	Z1302	HP210300P3	193838	Z1302	OB216300P2A1	629290	Z1302
CGAPREA1	630570	Z1302	HP216280P1	630412	Z1302	OB297300P	194560/R	Z1302
CGAPROFIL	630571	Z1302	HP5030/4	193831/R	Z1302	OB297300P1A1	629291	Z1302
CGAPROFILA1	630572	Z1302	HU12650	193847/R	Z1302	OB297300P1A2	629292	Z1302
CHI12160P	200144/R	Z1302	HU210150P	195968/R	Z1302	OB5020	195461/R	Z1302
COD.U5130	193711/R	Z1302	KB112100P	193855/R	Z1302	OB5540	195462/R	Z1302
COD.U9010	630548	Z1302	KO12675P	193858	Z1302	OD5045	195468/R	Z1302
CPI11075P	1619230	Z1302	KO216140P	630385	Z1302	OX21060	195472/R	Z1302
ET12645	196638/R	Z1302	KO216140P1	630386	Z1302	OX21660	629267	Z1302
ET209150P	193716/R	Z1302	MA216280P7	193863/R	Z1302	QU216280P	195473/R	Z1302
ET209300P	630364	Z1302	MA5030	193867/R	Z1302	QU216280P1	629265	Z1302
ET209300P1	630366	Z1302	MB21030	367494/R	Z1302	QU216280P1A1	195479/R	Z1302
ET21030	193764/R	Z1302	MED216280P	193869	Z1302	QU216280PA1	629261	Z1302
FAX21030	193725/R	Z1302	MED216300P	630384	Z1302	RE219280P	195481/R	Z1302
FAX21050	630453	Z1302	MET110150P	193874/R	Z1302	RE219280P1	629254	Z1302
FAX216100	630454	Z1302	MN216280P	193877/R	Z1302	RE219280PA1	195484/R	Z1302
FAX21630	630456	Z1302	MN216280P1	630379	Z1302	SH120100P	195487	Z1302
FAX21650	630457	Z1302	MN216280P2	630381	Z1302	SI216140P	629248	Z1302
FUD210295P4	193757/R	Z1302	MN220300P	193878/R	Z1302	SI6330	195488/R	Z1302
FUD216150P	193741	Z1302	NI216280P2	193889/R	Z1302	SL120150P	629229	Z1302

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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
SL120150P1	195490	Z1302	SO143150P1	631790	Z1302	SON216280P1	629189	Z1302
SL126150P	629227	Z1302	SO21550	195499/R	Z1302	ST5730	410830/R	Z1302
SL50120P	629231	Z1302	SO9224/1	195502/R	Z1302	SW120150P	195505/R	Z1302
SO143150P	200656	Z1302	SON216280P	195504/R	Z1302	VIT12525	175372/R	Z1302



CERTIFICATO n. **2139**
CERTIFICATE No

SI CERTIFICA CHE L'ORGANIZZAZIONE
WE HEREBY CERTIFY THAT THE ORGANIZATION

MODUL DIAGRAM SRL

IT - 48014 CASTELBOLOGNESE (RA) - VIA IV NOVEMBRE 337/347

NELLE SEGUENTI UNITA' OPERATIVE / IN THE FOLLOWING OPERATIVE UNITS

IT - 48014 CASTELBOLOGNESE (RA) - VIA IV NOVEMBRE 337/347

HA ATTUATO E MANTIENE UN SISTEMA DI GESTIONE QUALITA' CHE E' CONFORME ALLA NORMA
HAS IMPLEMENTED AND MAINTAINS A QUALITY MANAGEMENT SYSTEM WHICH COMPLIES WITH THE FOLLOWING STANDARD

UNI EN ISO 9001:2008

PER LE SEGUENTI ATTIVITA' / FOR THE FOLLOWING ACTIVITIES **SETTORE** **IAF 19**
CODE

Produzione e commercializzazione di supporti ed accessori di registrazione per applicazioni medicali, elettrodi, gel sterili e non per la trasmissione ad ultrasuoni, gel non sterili per la trasmissione di segnali elettrici, boccagli respiratori, sistemi barriera e di imballaggio per dispositivi medici da sterilizzare terminalmente.

Manufacturing and sale of charts and accessories for medical recording applications, electrodes, sterile and non sterile ultrasonic transmission gel, non sterile electrical transmission gel, respiratory mouthpieces, barrier systems and packaging for terminally sterilized medical devices.

RIFERIRSI AL MANUALE DI GESTIONE QUALITA' PER L'APPLICABILITA' DEI REQUISITI DELLA NORMA
REFER TO MANAGEMENT SYSTEM MANUAL FOR DETAILS OF APPLICATION TO STANDARD REQUIREMENTS

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR THE CERTIFICATION OF MANAGEMENT SYSTEMS

PRIMA EMISSIONE **20/04/1999**
FIRST ISSUE
EMISSIONE CORRENTE **09/02/2017**
CURRENT ISSUE
DATA SCADENZA **14/09/2018**
EXPIRY DATE

CERTIQUALITY S.r.l. - IL PRESIDENTE
Via G. Giardino 4 - 20123 MILANO (MI) - ITALY



SGQ n. 008 A SSI N. 007 G
SGA n. 001 D SGE N. 001 M
SCR n. 002 F ISF N. 006 O
FSM n. 006 I EMAS N. 008 P
PRD n. 008 B ITX N. 004 L
DAP n. 003 H
PRS n. 100 C

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

C01 ED 03 010616

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THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

For information concerning the validity of the certificate, you can visit the site www.certiquality.it

The validity this certificate depends on annual audit and on a complete review every three years of the Management System.



www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale. CISQ is the Italian Federation of management system Certification Bodies.



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and its partner
CISQ/CERTIQUALITY S.r.l.

MODUL DIAGRAM SRL

IT - 48014 CASTELBOLOGNESE (RA) - VIA IV NOVEMBRE 337/347

has implemented and maintains a

Quality Management System

which fulfills the requirements of the following standard

ISO 9001:2008

for the following activities

Code **IAF 19**

Manufacturing and sale of charts and accessories for medical recording applications, electrodes, sterile and non sterile ultrasonic transmission gel, non sterile electrical transmission gel, respiratory mouthpieces, barrier systems and packaging for terminally sterilized medical devices.

in the following operative units

IT - 48014 CASTELBOLOGNESE (RA) - VIA IV NOVEMBRE 337/347

Issued on: **2017-02-09**

Certified since: **1999-04-20**

Expire on: **2018-09-14**

Registration number: **IT-6698**



Michael Drechsel

President of IQNET



Ing. Claudio Provetti

President of CISQ

IQNet Partners**:

AENOR Spain AFNOR Certification France Vinçotte Belgium APCER Portugal CCC Cyprus
CISQ Italy CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia IMNC Mexico Inspecta Certification Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland PCBC Poland
Quality Austria Austria RR Russia SIGE México SII Israel SIQ Slovenia SIRIM QAS International Malaysia
SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc..

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.ionet-certification.com