



DECLARATION OF CONFORMITY

RECORDING PAPER WITH 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 with measuring function for medical equipments", and in particular the codes covered in this family are:

UMDNS CODES:

- 16754 Paper, Recording, ECG
- 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 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 VII 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 is manufactured and commercialised with date of first introduction 23/04/99 and lot No. 01799 as declared in the product technical issue within the limits of the application of a Company quality system declared consistent with the UNI EN ISO 9001:2008 regulations by Certiquality, Notified Body according to Directive 93/42/CEE with No. 0546, according to what prescribed by the Enclosure V of the above mentioned Directive (with reference exclusively to the measuring function) and as mentioned in the Certificate n.2139/CE001/1 dated 17.03.2009 (first issue dated 20.04.1999), and here attached.

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/CE001/1

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
01274	198924	Z1302	01350	199035	Z1302	01616	632297	Z1302
01275	633394	Z1302	01356	631927	Z1302	01619	199200	Z1302
01278	633395	Z1302	01357	631928	Z1302	01623	632288	Z1302
01279	633397	Z1302	01359	631929	Z1302	01624	632289	Z1302
01281	633399	Z1302	01361	632337	Z1302	01625	632290	Z1302
01282	198942	Z1302	01367	199038	Z1302	01626	199308	Z1302
01283	632908	Z1302	01368	631907	Z1302	01627	199205	Z1302
01284	632910	Z1302	01372	632339	Z1302	01638	632280	Z1302
01285	632911	Z1302	01374	631908	Z1302	01641	632667	Z1302
01288	632927	Z1302	01377	199110	Z1302	01642	632707	Z1302
01289	198946	Z1302	01378	633406	Z1302	01644	632727	Z1302
01291	632789	Z1302	01381	633407	Z1302	01647	199207	Z1302
01292	199288	Z1302	01388	633408	Z1302	01650	632323	Z1302
01294	632790	Z1302	01393	633409	Z1302	01652	632728	Z1302
01298	632792	Z1302	01399	199126	Z1302	01658	632324	Z1302
01301	198949	Z1302	01401	632352	Z1302	01686	632327	Z1302
01303	632888	Z1302	01402	632340	Z1302	01698	632747	Z1302
01304	632889	Z1302	01404	632354	Z1302	01706	199314	Z1302
01306	632890	Z1302	01412	632358	Z1302	01707	632317	Z1302
01307	632891	Z1302	01416	199131	Z1302	01708	632318	Z1302
01313	198954	Z1302	01420	632341	Z1302	01783	199215	Z1302
01316	632829	Z1302	01424	199302	Z1302	01787	632311	Z1302
01317	632847	Z1302	01425	631930	Z1302	01789	632312	Z1302
01318	632867	Z1302	01427	631947	Z1302	01797	632313	Z1302
01320	198956	Z1302	01431	632330	Z1302	01799	632315	Z1302
01321	632807	Z1302	01433	631968	Z1302	01819	632590	Z1302
01323	632808	Z1302	01434	631970	Z1302	01825	199218	Z1302
01324	632809	Z1302	01437	631971	Z1302	01827	632592	Z1302
01326	632810	Z1302	01515	632210	Z1302	01830	632267	Z1302
01327	199027	Z1302	01516	199137	Z1302	01835	632268	Z1302
01329	633425	Z1302	01518	632331	Z1302	01878	632607	Z1302
01332	633427	Z1302	01532	632286	Z1302	01887	632608	Z1302
01335	633429	Z1302	01533	632332	Z1302	02128	199233	Z1302
01336	633430	Z1302	01537	632333	Z1302	02148	199226	Z1302
01337	199030	Z1302	01544	632334	Z1302	02178	632301	Z1302
01339	633414	Z1302	01550	199140	Z1302	02197	632309	Z1302
01341	633415	Z1302	01609	199148	Z1302	02198	632306	Z1302
01342	633417	Z1302	01612	632292	Z1302	02266	632302	Z1302
01344	633419	Z1302	01613	632293	Z1302	02345	632303	Z1302
01346	632336	Z1302	01615	632295	Z1302	02368	199315	Z1302



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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
02373	632257	Z1302	874.5555	632975	Z1302	BO12030	196658	Z1302
02485	632304	Z1302	8745556	632797	Z1302	BO130135P	199382	Z1302
02489	199318	Z1302	8745558	632214	Z1302	BO135100P	199382	Z1302
02519	199235	Z1302	8.745.559	196616	Z1302	BO14530/2	196661	Z1302
02566	632255	Z1302	874.6540	632215	Z1302	BO14560/2	196662	Z1302
02576	632249	Z1302	874.6556	632798	Z1302	BO13530/1	628363	Z1302
02589	199236	Z1302	00038	198911	Z1302	BR108140P	1128133	Z1302
02591	199319	Z1302	00048	632207	Z1302	BR10823	196667	Z1302
02592	632251	Z1302	00057	632208	Z1302	BR13530	628590	Z1302
02593	632611	Z1302	00058	632209	Z1302	BR140100P	199383	Z1302
02610	632307	Z1302	00471	196623	Z1302	BR14030	196670	Z1302
02612	196625	Z1302	874.3550	196620	Z1302	BR21020	1619227	Z1302
02668	199246	Z1302	AL14230	196628	Z1302	BR21020A1	1619163	Z1302
02675	632362	Z1302	AL14230A1	629177	Z1302	BR210296S1	1501152	Z1302
02692	632363	Z1302	AMS120100P	199369	Z1302	BR210300P	199385	Z1302
02706	199250	Z1302	AMS120100P1	632380	Z1302	BR210300P2	1066727	Z1302
02794	632371	Z1302	AMS120100P2	632384	Z1302	BR210300P3	1242640	Z1302
02883	199324	Z1302	AMS150100P	632386	Z1302	BR210300PA1	410767	Z1302
02884	632567	Z1302	AMS90100P	632396	Z1302	BR215280P	633400	Z1302
02885	632568	Z1302	AP6225	277591	Z1302	BR215280P1	633401	Z1302
02891	632569	Z1302	AP720	1619249	Z1302	BR215280P2	210285	Z1302
02945	632570	Z1302	ASC11010	196631	Z1302	BR215280P2A1	1242638	Z1302
02946	632587	Z1302	ASC11225	629175	Z1302	BR215280P3	633402	Z1302
02947	199329	Z1302	ASC21025	1335810	Z1302	BR215280P3A2	200376	Z1302
02948	633374	Z1302	ASC210140P	199377	Z1302	BR21550	196684	Z1302
02989	633375	Z1302	ASC5818	1619118	Z1302	BR21550/1A1	196686	Z1302
02999	633377	Z1302	ASC5825	196633	Z1302	BR280215P	633403	Z1302
03000	199252	Z1302	ASC6025	196636	Z1302	BR296215P	633404	Z1302
03026	199257	Z1302	AT12645	197633	Z1302	BR5070P	199388	Z1302
03034	633380	Z1302	AVEC4	196639	Z1302	BRED14	199390	Z1302
03062	632612	Z1302	AVEC5	628702	Z1302	BRED24	631627	Z1302
03118	632260	Z1302	BC13030	196642	Z1302	BU106140P	199393	Z1302
03119	632343	Z1302	BC14030	628695	Z1302	BU210300P	199417	Z1302
03155	633381	Z1302	BC5530	196644	Z1302	BU210300P1	631587	Z1302
03181	199259	Z1302	BCR112140P	1619131	Z1302	BU21545/1	196689	Z1302
03222	632287	Z1302	BCR210150P	1619140	Z1302	BU21545/1A1	196691	Z1302
04149	1619153	Z1302	BH60120P	1619229	Z1302	BU21545/2	628577	Z1302
04323	1619156	Z1302	BD9130	196645	Z1302	BU216140P	199422	Z1302
04389	1619157	Z1302	BI11030	199378	Z1302	BU216280P	631607	Z1302
04832	1619158	Z1302	BIO216140P	199378	Z1302	BU216280PA1	1619216	Z1302
874.3523	626254	Z1302	BNT15225A2	1619162	Z1302	BU216280P1	631608	Z1302
874.5553	198903	Z1302	BNT21515	196651	Z1302	BU5030/1	196695	Z1302
874.5554	198908	Z1302	BNT21525	196654	Z1302	BU5045	196695	Z1302



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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
BU5046A1	196697	Z1302	CGR5030	197557	Z1302	ET112100P	200154	Z1302
BTL210150P	1406663	Z1302	CGR5035	629187	Z1302	ET120100PA1	200252	Z1302
BTL210280P	1335811	Z1302	CGR6330	197558	Z1302	ET12020	197593	Z1302
BYS112120P	199425	Z1302	CHI13040	197559	Z1302	ET12030	629907	Z1302
BYS11225	1619165	Z1302	CL10525	1619169	Z1302	ET13025	197617	Z1302
BYS21625	196699	Z1302	CL10622	1619170	Z1302	ET13415	629867	Z1302
CA110150P	1400390	Z1302	CL6325	1619171	Z1302	ET13430	629868	Z1302
CA112100P	199430	Z1302	CM15290P	367473	Z1302	ET209140P	771727	Z1302
CA11230	1619167	Z1302	CM15290P1	1619141	Z1302	ET209150P1	200255	Z1302
CA12030	196701	Z1302	CO130120P1	200148	Z1302	ET209150P1A1	631387	Z1302
CA12530	628433	Z1302	CO140120P	631448	Z1302	ET209150PA1	631407	Z1302
CA12550	628435	Z1302	CO14030	197562	Z1302	ET20920/1	197619	Z1302
CA130135P	631547	Z1302	CO14030/1	629971	Z1302	ET20920/2	1619245	Z1302
CA134100P	200047	Z1302	CO152120P1	200150	Z1302	ET20920/1A1	197622	Z1302
CA13430	196703	Z1302	CO15290P1	631449	Z1302	ET210280P	1527728	Z1302
CA15550	196708	Z1302	CO15290P2	631450	Z1302	ET5015	197626	Z1302
CA16230	196711	Z1302	CON11020P	1619172	Z1302	ET5030	629807	Z1302
CA183260P	631467	Z1302	CON5020	1619173	Z1302	ET5030A1	629808	Z1302
CA183260PA2	631487	Z1302	COS30025	197563	Z1302	ET5730	197631	Z1302
CA18330	626256	Z1302	CTG112100P	1619142	Z1302	ET6015	629809	Z1302
CA210280P	631488	Z1302	CU210150P	200152	Z1302	ET6075P	631427	Z1302
CA210280P2	161913	Z1302	CW11025	1619204	Z1302	FU13075P	200263	Z1302
CA210280PA1	1619133	Z1302	CW11225	410768	Z1302	FUD14575P1	1619145	Z1302
CA210280PA2	1619134	Z1302	CW6330	1619174	Z1302	FU145150P	631347	Z1302
CA210295P	1400392	Z1302	CW8020	410772	Z1302	FU145150P1	631348	Z1302
CA21030	626257	Z1302	DI64178P	200153	Z1302	FU145150P2	631367	Z1302
CA24250	196716	Z1302	DL11830	197575	Z1302	FU145150PA1	631007	Z1302
CA4530	629727	Z1302	DL11830/1A1	277604	Z1302	FU145150PA2	200269	Z1302
CA5030	105434	Z1302	DL12030	629967	Z1302	FU210150P1	631007	Z1302
CA5030/2	196720	Z1302	DL6330	629968	Z1302	FU5030/1	629708	Z1302
CA5730	626252	Z1302	DO12645	197585	Z1302	FU5070P	630747	Z1302
CA60100P	631549	Z1302	DO6330	629949	Z1302	FU63100P	630767	Z1302
CA6030	196722	Z1302	DO6345	629950	Z1302	FU63100P1	630768	Z1302
CAM216280P2	200139	Z1302	ED11290P	1619143	Z1302	FU63100P2	200273	Z1302
CAM216280P3	631452	Z1302	ED11290P1	1619144	Z1302	FUD6330/3	1619177	Z1302
CAM216280P4	200141	Z1302	ED15290P	367474	Z1302	FUD110140P	200282	Z1302
CAM21646/2	196727	Z1302	ED210140P	1065386	Z1302	FUD13030	197634	Z1302
CAM21646/3	196732	Z1302	ED210295P	779948	Z1302	FUD13530	629748	Z1302
CAM21646/3A1	629547	Z1302	ED215280P	1335814	Z1302	FUD145150P1	631288	Z1302
CAM4830	197550	Z1302	ED21530	1464525	Z1302	FUD145250P	631289	Z1302
CAM5460	630007	Z1302	ED5025	410774	Z1302	FUD14530/1A1	629749	Z1302
CGA13425A1	197553	Z1302	ED8020	1619175	Z1302	FUD14530/1A2	629768	Z1302
CGAAT3	197554	Z1302	ED8030	1619176	Z1302	FUD14530/1A3	629751	Z1302



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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
FUD14530/2	197644	Z1302	HE250200PI	200331	Z1302	KB120100P	200357	Z1302
FUD14530/2A1	629305	Z1302	HE25050	629424	Z1302	KB140100P	200358	Z1302
FUD14530/3	629306	Z1302	HE5050	629429	Z1302	KB95100P	631076	Z1302
FUD14575P	631307	Z1302	HE5430	197666	Z1302	KE11227	197676	Z1302
FUD20030	629753	Z1302	HE5440	629410	Z1302	KE11290P	200361	Z1302
FUD210145P	200284	Z1302	HE8090P	410765	Z1302	KE11290P1	1619148	Z1302
FUD210295P	631647	Z1302	HE8090PA1	410775	Z1302	KE183130P	631069	Z1302
FUD210295P1	631667	Z1302	HE9030	629414	Z1302	KE183280P	200364	Z1302
FUD210295P2A1	200286	Z1302	HE9090P	200337	Z1302	KE18330A1	197680	Z1302
FUD210295P3	200287	Z1302	HE9090PA1	1335795	Z1302	KE210145P	1619149	Z1302
FUD210295P3A2	1335804	Z1302	HP120150P	200338	Z1302	KE210150P1	1619150	Z1302
FUD21030	197648	Z1302	HP120150P2	200341	Z1302	KE21030	529368	Z1302
FUD21030/1	629567	Z1302	HP12060	197670	Z1302	KE210300P1	1619135	Z1302
FUD210300P	200289	Z1302	HP14160	629391	Z1302	KO14475P	200365	Z1302
FUD27830	629568	Z1302	HP151100P2	200343	Z1302	MA10846	197682	Z1302
FUD5030	629587	Z1302	HP151100P3	631167	Z1302	MA18745	277589	Z1302
FUD5030/1	629708	Z1302	HP151100P5	200346	Z1302	MA210280P	200366	Z1302
FUD5030/1A1	197652	Z1302	HP151100P6	631168	Z1302	MA210280PA1	200367	Z1302
FUD5030/1A2	197655	Z1302	HP151100P6/E	1619147	Z1302	MA210280PA2	1619506	Z1302
FUD5030/2	630009	Z1302	HP151100P7	631147	Z1302	MA216280P10	200371	Z1302
FUD5075P	200291	Z1302	HP151100P8	631148	Z1302	MA216280P3	633207	Z1302
FUD63100P2	631247	Z1302	HP210297S1	1619248	Z1302	MA216280P3A1	633208	Z1302
FUD6330/1	197658	Z1302	HP210300P1	200350	Z1302	MA216280P3A2	200376	Z1302
FUD6330/2	629435	Z1302	HP210300P2	631108	Z1302	MA216280P3A3	1619218	Z1302
FUD6330/2A1	629440	Z1302	HP210300P2A1	631109	Z1302	MA216280P4	200377	Z1302
GR5750	193777	Z1302	HP21460/2	196638	Z1302	MA216280P4A1	631847	Z1302
HE10050	197662	Z1302	HP216280P2	631110	Z1302	MA216280P4A2	631327	Z1302
HE11050	197665	Z1302	HP216280P3	410769	Z1302	MA216280P5	631328	Z1302
HE110140P1	1336359	Z1302	HP216300P	631127	Z1302	MA216280P6	631329	Z1302
HE110140P1A1	1335794	Z1302	HP4530	277586	Z1302	MA21645	629338	Z1302
HE120150P	200300	Z1302	HP5030/1	629390	Z1302	MA21670/1	629342	Z1302
HE120150P1	631208	Z1302	HP5030/2	629393	Z1302	MA21676	629345	Z1302
HE13050	629422	Z1302	HP5030/3	629394	Z1302	MDC10925	197684	Z1302
HE170150P	631210	Z1302	HP63150P	200352	Z1302	MG11030	558787	Z1302
HE170150P1	631211	Z1302	HP63150P1	631088	Z1302	MG11230	1335798	Z1302
HE18050	200300	Z1302	HP6360/1	629396	Z1302	MG215280P	1335797	Z1302
HE19050	629423	Z1302	ID11225	1619178	Z1302	MK130120P	1335799	Z1302
HE207135P	631227	Z1302	ID11230	197671	Z1302	MM8015	1619180	Z1302
HE210295P	200320	Z1302	ID5825	197673	Z1302	MM11225	1684107	Z1302
HE210295P1	1335806	Z1302	ID8020	1619179	Z1302	MN12645	197687	Z1302
HE210300P	631188	Z1302	ID8030	629387	Z1302	MND215280P	1357716	Z1302
HE210300PA1	410766	Z1302	IM21445	197675	Z1302	MO12760	197688	Z1302
HE250200P	200326	Z1302	IN120120P	200353	Z1302	MQ5715	197689	Z1302



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MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
MQ5730	197691	Z1302	OB14275P	200594	Z1302	PH210300P	200611	Z1302
MT11430	1619181	Z1302	SH210280PA1	633171	Z1302	SO9224	197835	Z1302
MWZ110100P	200382	Z1302	OB210140P	1619136	Z1302	PH210300PA1	1619221	Z1302
MWZ11030	197694	Z1302	OB210150P1	200590	Z1302	PH210300PA1/1	1619222	Z1302
MWZ15050	197696	Z1302	OB210150P4	633355	Z1302	PH5020	197741	Z1302
MWZ210150P	633369	Z1302	OB210150P4A2	633356	Z1302	PH7530	1619183	Z1302
MWZ21030/1	197697	Z1302	OB210150P5	633336	Z1302	PH79150P	631850	Z1302
MWZ21050/1	629328	Z1302	OB210280P	200601	Z1302	PO18850	197742	Z1302
MY135100P	633370	Z1302	OB210280P1	633337	Z1302	PO25050	197745	Z1302
NEC145125P	633371	Z1302	OB210280P1A1	1619219	Z1302	PR6015	197775	Z1302
NIED24	200521	Z1302	OB210280P2	1109753	Z1302	PR11030	1619184	Z1302
NK110140P2	1619199	Z1302	OB210280P3	1619137	Z1302	PR112100P	1335802	Z1302
NK13530	197701	Z1302	OB210280P4A1	1619220	Z1302	QU210300P	200616	Z1302
NK145100P	200581	Z1302	OB210280PA1	633323	Z1302	QU210300P1A1	1335801	Z1302
NK145125P	631887	Z1302	OB210300P1	633344	Z1302	QU216280P2	633247	Z1302
NK14530/2	631267	Z1302	OB210300P2	200604	Z1302	QU216280P2A1	200618	Z1302
NK14560	631268	Z1302	OB210300P2A1	631869	Z1302	QU216280P3	633317	Z1302
NK14575P	631888	Z1302	OB26030	630370	Z1302	QU216280P4	633320	Z1302
NK15090P	631889	Z1302	OB3618	630371	Z1302	QU216280P4A1	200619	Z1302
NK150100P	629993	Z1302	OB5030	630372	Z1302	QU216280P5	1242656	Z1302
NK15090P	631889	Z1302	OB5030/1	197716	Z1302	QU21645/1	197778	Z1302
NK210140P2	410771	Z1302	OB5030A1	632243	Z1302	QU21645/3	197780	Z1302
NK210295P	200583	Z1302	OB8070P	631871	Z1302	SA13230	197782	Z1302
NK210300P2	200585	Z1302	OB9028	632244	Z1302	SE13930	197791	Z1302
NK21060	197707	Z1302	OB9070P	633324	Z1302	SE4930	632234	Z1302
NK216150P	633358	Z1302	OB9070PA1	633326	Z1302	SEW114100P	631827	Z1302
NK216280P	633359	Z1302	OB9070PA2	834668	Z1302	SH145150P	1619203	Z1302
NK216300P	633361	Z1302	OD6175P	200605	Z1302	SH13030	197794	Z1302
NK216300P1	633353	Z1302	OL117150PA1	200607	Z1302	SH135140P	200623	Z1302
NK21660	632400	Z1302	OS4830	197718	Z1302	SH135140P1A1	631688	Z1302
NK21660/1	632403	Z1302	PC10825	197719	Z1302	SH145100P	631689	Z1302
NK21660/2	632404	Z1302	PC10825/1	197721	Z1302	SH145100PA1	631707	Z1302
NK28060	631269	Z1302	PC4216	632241	Z1302	SH210140P	631727	Z1302
NK50100P	633365	Z1302	PC4216A1	197733	Z1302	SH210140P2A1	200626	Z1302
NK5030/2	231270	Z1302	PC5020	197733	Z1302	SH210140P3	633227	Z1302
OB10030	197712	Z1302	PC5030A1	197734	Z1302	SH210150P1	200630	Z1302
OB11495P1	1402857	Z1302	PE12530	197737	Z1302	SH210150P1A1	633387	Z1302
OB126150P	200588	Z1302	PE21030	632237	Z1302	SH210150P2	633389	Z1302
OB126150P1	200590	Z1302	PE5023	197738	Z1302	SH210150P3	633390	Z1302
OB126150PA1	633351	Z1302	PE5030	197740	Z1302	SH210280P	200632	Z1302
OB126150PA2	633353	Z1302	PH11025	1619182	Z1302	SH210280P1	633169	Z1302
OB13330	630368	Z1302	PH132150P	200610	Z1302	SH210280P1A1	633170	Z1302
OB14230	630369	Z1302	PH170125P	631849	Z1302	SH210280P1A2	633228	Z1302



**DECLARATION OF CONFORMITY
RECORDING PAPER WITH MEASURING FUNCTION
FOR MEDICAL EQUIPMENTS**

modul diagram CE marked

MD REF	Repertorio	CND	MD REF	Repertorio	CND	MD REF	Repertorio	CND
SH210280P1A3	633229	Z1302	SI147100P1	633015	Z1302	SO139150P1	632948	Z1302
SH210280PA2	633230	Z1302	SI14725	197810	Z1302	SO139150P2	632949	Z1302
SH70100P	200636	Z1302	SI18050	632230	Z1302	SO9224/2	632219	Z1302
SH70100PA1	633158	Z1302	SI210150P	200647	Z1302	SWA210150P	200658	Z1302
SH9090P	633159	Z1302	SI210150P1	632987	Z1302	SWA210300P	200659	Z1302
SH9090P1	633161	Z1302	SI210300P	632990	Z1302	TOI151120P	200663	Z1302
SH9090PA1	1619223	Z1302	SI210300P1	632989	Z1302	TOI151120P1	200668	Z1302
SH9090P1A1	633163	Z1302	SI210300PA1	632992	Z1302	TOI151150P	631787	Z1302
SH9090P2	200639	Z1302	SI210300PA2	200650	Z1302	TOI151150P1	631767	Z1302
SH9090P3	631807	Z1302	SI216280P	1619139	Z1302	TOI151150P2	1335792	Z1302
SH9090P3A1	631827	Z1302	SI21650	197813	Z1302	V2-20.200	1619251	Z1302
SI10050	197804	Z1302	SI5025	197816	Z1302	VIT198218W1	1619253	Z1302
SI104100P	200643	Z1302	SI5050/3	197817	Z1302	VO12830	197840	Z1302
SI104100P1	633008	Z1302	SI5950	632231	Z1302	WAK100100P	200670	Z1302
SI11050	197804	Z1302	SI6375P	633017	Z1302	WAK145100P	632245	Z1302
SI12350	197808	Z1302	SL6330	197821	Z1302	WE11420	1619185	Z1302
SI125125P	633010	Z1302	SM21650	197824	Z1302	WE11470P	410763	Z1302
SI145150P	200645	Z1302	SM30025	197827	Z1302	WE210280P	1619224	Z1302
SI145150PA1	633012	Z1302	SO11330	197833	Z1302	WE210280P1	1619225	Z1302
SI147100P	633013	Z1302	SO139150P	200654	Z1302	ZO9090P	200673	Z1302



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ

ORGANISMO NOTIFICATO N° 0546
NOTIFIED BODY N° 0546

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

MODUL DIAGRAM SRL

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

UNITA' OPERATIVE
OPERATING SITES

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

PER I SEGUENTI TIPI / FAMIGLIE DI PRODOTTI
FOR THE FOLLOWING TYPES / CLASSES OF PRODUCTS


Carta da registrazione, con funzione di misura, per apparecchiature elettromedicali.

Registration charts, with measuring function, for electromedical equipment.

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema garanzia qualità
Certiquality S.r.l., Notified Body n° 0546, certifies that the quality assurance system
è conforme ai requisiti della Direttiva 93/42 CEE, Allegato V
is in compliance with the requirements of Council Directive 93/42/CEE, Annex

CERTIFICATO N. **2139/CE001/2**
CERTIFICATE N.

PRIMA EMISSIONE **20/04/1999**
FIRST ISSUE
EMISSIONE CORRENTE **13/03/2014**
CURRENT ISSUE
DATA DI SCADENZA **12/03/2019**
EXPIRY DATE


IL PRESIDENTE

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
Via Gaetano Giardino 4 - 20123 Milano - tel. 02 8069171 - fax 02 86465295 - certiquality@certiquality.it - www.certiquality.it