



M.D.L. Srl  
Via Tavani 1/a – 23014 – Delebio (So) - Italy  
Tel (+39) 0342 / 682130 Fax (+39) 0342 / 691316  
P.IVA e Cod. Fiscale 00656810140 Cod. Rea : 46278  
e\_mail: info@mdlsrl.com web:www.mdlsrl.com

**Subject:**

**"LEGACY DEVICE" Declaration - REGULATION (EU) 2023/607  
Extension of the expiry date of the CE Certificate No. 166-02-03-DM**

The undersigned M.D.L. S.r.l. (SRN: IT-MF-000011599), having its registered office in Via Tavani 1/A - 23014 Delebio (SO) - Italy, declares under its sole responsibility that the medical devices listed in the CE Certificate No. 166-02-03-DM (expire date 19/12/2023) issued by the Notified Body "Italcert S.r.l." (No. 0426), are in accordance with REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

The CE Certificate No. 166-02-03-DM is therefore valid beyond its natural expiry date until 26<sup>th</sup> May 2024 for all the medical device codes listed in it.

After 26<sup>th</sup> May 2024 the CE Certificate will be valid at least for the codes listed in the table below until 31<sup>st</sup> December 2028:

Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PILXXYY/ZZ	Illy	Ila	Ila
PJXXYY	OsteoJ	Ila	Ila
PJHXXYY	OsteoJ, OsteoJH	Ila	Ila
PIXXXYY/ZZ	PenBone	Ila	Ila
PIGXXYY/ZZ	Pen-Bone	Ila	Ila
PIPXXYY/ZZ	PenBone Blu	Ila	Ila
PJTXXYY	PickUp	Ila	Ila
PJTHXXYY	PickUp, Pick-Up	Ila	Ila
PJTDXXYY	PickUpD	Ila	Ila
PJK2XXYY	JamBlu	Ila	Ila
PJK2HXXYY	JamBlu	Ila	Ila
PSXXYY	PressTo	Ila	Ila
PSH1D2XXYY	CellColt	Ila	Ila
PJEXXXYY	Harvest	Ila	Ila
PIEXXXYY/ZZ	PenBoneE	Ila	Ila



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Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PILEXXYY/ZZ	IllyE	Ila	Ila
PC0XXYY	EasyCut	Ila	Ila
PCXXYY	EasyLock	Ila	Ila
PMXXYY	HandCut	Ila	Ila
PAXXXY	EpaSet	Ila	Ila
VEXXYY	MDCut E, FastCutE	Ila	Ila
VESXXYY	FastCutS	Ila	Ila
MGXXYY	FastCutM	Ila	Ila
MGPXXYY	MDCut P, FastCutP	Ila	Ila
MGPCXXYY	FastCutP	Ila	Ila
MGK1XXYY	Palium Needle	Ila	Ila
MGCXXYY	Palium Needle, PaliumCoaxial	Ila	Ila
PDXXYY	LightCut Plus	Ila	Ila
PD0XXYY	SemiCut	Ila	Ila
PD0MRXXYY	SemiCut MRI	Ila	Ila
PD0PPXXYY	SemiCut, SemiCut Coax.	Ila	Ila
TYXXYY	Themy	Ila	Ila
TYSXXYY	ThemyS	Ila	Ila
TYSCXXYY	ThemySC	Ila	Ila
TYCXXYY	Themy, ThemyC	Ila	Ila
TYQXXYY	ThemyQ	Ila	Ila
TYQCXXYY	ThemyQC	Ila	Ila
PTXXYY	Intro	Ila	Ila
PTMXXYY	Intro	Ila	Ila
PL	Palium	Ila	Ila
PBXXYY	CytoCut	Ila	Ila
PBMXXYY	CytoCut	Ila	Ila
PBQXXYY	CytoCut	Ila	Ila
PBUXXXY	Amnio	Ila	Ila
PBUTXXYY	ChorionSet	Ila	Ila
PEFXXYY	Franseen	Ila	Ila
PEWXXYY	Wescott	Ila	Ila
AETNXXXXY	StimyEcho	Ila	Ila
AETNFXXXXY	StimyEcho	Ila	Ila
AEQNXXXXY	StimyEcho	Ila	Ila
AEQNFXXXXY	StimyEcho	Ila	Ila
AEYNXXXXY	StimyEcho	Ila	Ila
AEYNFXXXXY	StimyEcho	Ila	Ila



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Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
AETMNXXXXY	StimyEcho16	Ila	Ila
AEYMNXXXXY	StimyEcho20	Ila	Ila
AEQMNXXXXY	StimyEcho30	Ila	Ila
AETHXXXXY	StimyPlus	Ila	Ila
AETHFXXXXY	StimyPlus	Ila	Ila
AETMXXXXY	StimyPlus16	Ila	Ila
AEYMXXXXY	StimyPlus20	Ila	Ila
AEQMXXXXY	StimyPlus30	Ila	Ila
AEQHXXXXY	StimyPlus	Ila	Ila
AEQHFXXXXXY	StimyPlus	Ila	Ila
AEYHXXXXY	StimyPlus	Ila	Ila
AEYHFXXXXY	StimyPlus	Ila	Ila
AETRXXXXY	StimyUltra, StimyUltra16	Ila	Ila
AETRFXXXXY	StimyUltra	Ila	Ila
AEQRXXXXY	StimyUltra, StimyUltra30	Ila	Ila
AEQRFXXXXY	StimyUltra	Ila	Ila
AEYRXXXXY	StimyUltra, StimyUltra20	Ila	Ila
AEYRFXXXXY	StimyUltra	Ila	Ila
AEYMVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQMVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYHVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQHVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYMVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQMVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AETHVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQHVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYMNvXXXXY	VygoPlex Echo	Ila	Ila
AEQMNVXXXXY	VygoPlex Echo	Ila	Ila
AEYNvXXXXY	VygoPlex Echo	Ila	Ila
AEQNVXXXXY	VygoPlex Echo	Ila	Ila
AEYMNvFXXXXXY	VygoPlex Echo	Ila	Ila
AEQMNVFXXXXXY	VygoPlex Echo	Ila	Ila
AEYNvFXXXXXY	VygoPlex Echo	Ila	Ila
AEQNVFXXXXXY	VygoPlex Echo	Ila	Ila
PNXXXXY	Mark	Ila	Ila
PNXXXXY	MarkX	Ila	Ila



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Medical Device Code	Commercial Name	MDD 93/42/CEE Risk Class	MDR 2017/745 Risk Class
PNZXXYY	MarkZ	Ila	Ila
PNSXXYY	MarkSlim	Ila	Ila
PNAXXXYY	AutoMark	Ila	Ila
PNAXXXYY	AutoMarkX	Ila	Ila
PRXXYY	RepoMark	Ila	Ila
PRDXXYY	RepoMarkD	Ila	Ila
AVAXXXYY	VeressA	Ila	Ila
AVAQXXYY	VeressQ	Ila	Ila
AVBXXYY	VeressB	Ila	Ila
AVBQXXYY	VeressQ	Ila	Ila
AVCXXYY	VeressC	Ila	Ila
AVCQXXYY	VeressQ	Ila	Ila
AV01TXX	ToraSet	Ila	Ila
AV01XXYYA	ToraSet	Ila	Ila
AV01XXYYB	ToraSet	Ila	Ila
AV01XXYYC	ToraSet	Ila	Ila
AV02TXX	ToraSetValve	Ila	Ila
AV02XXYYA	ToraSetValve	Ila	Ila
AV02XXYYB	ToraSetValve	Ila	Ila
AV02XXYYC	ToraSetValve	Ila	Ila
AV01KS	ParaSet	Ila	Ila
AV02KS	ParaSet	Ila	Ila
PZYDXXYY	GalaKitDuo	Ila	Ila
PZYCXXYY	GalaKitDuo	Ila	Ila
RF0MXXYYRZZα	RF Probe IE	Ila	Ila
RFMXXYYRZZα	RF Probe	Ila	Ila
LPXXYYRZ	Lipo	Ila	Ila
LPXXYYZ	Lipo	Ila	Ila

Delebio, 19.12.2023

Signature

**M.D.L. SRL**  
Via Tavani, 1/A  
23014 DELEBIO (SO), Italia  
C.F./P.IVA 00656810140  
Marcello Dell'Oca  
(CEO and PRRC of M.D.L. S.r.l.)



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Tłumaczenie z języka angielskiego

**Temat:**

**Deklaracja „LEGACY DEVICE” ROZPORZĄDZENIE (UE) 2023/607**

**Przedłużenie terminu ważności Certyfikatu CE nr 166-02-03-DM**

Niniej podpisany M.D.L. S.r.l. (SRN: IT-MF-000011599), z siedzibą przy Via Tavani 1/A – 23014 Delebio (SO) – Włochy, oświadcza na swoją wyłączną odpowiedzialność, że wyroby medyczne wymienione w Certyfikacie CE Nr 166-02-03-DM (ważny do dnia 19.12.2023 r.) wydane przez Jednostkę Notyfikowaną „Italcert S.r.l. (nr 0426), są zgodne z ROZPORZĄDZENIEM PARLAMENTU I RADY EUROPEJSKIEJ (UE) 2023/607 z dnia 15 marca 2023 r. zmieniającym rozporządzenie (UE) 2017/745 i (UE) 2017/746 w zakresie przepisów przejściowych dla niektórych wyrobów medycznych i wyrobów do diagnostyki in vitro.

Certyfikat CE nr 166-02-03-DM jest zatem ważny po swojej naturalnej dacie ważności do 26 maja 2024 r. dla wszystkich wymienionych w nim kodów wyrobów medycznych.

Po 26 maja 2024 r. Certyfikat CE będzie ważny dla kodów wymienionych w poniższej tabeli do 31 grudnia 2028 r.

Kod produktu medycznego	Nazwa handlowa	MDD 93/42/CEE Klasa ryzyka	NDR 2017/745 Klasa ryzyka
PILXXYY/ZZ	Illy	Ila	Ila
PJXXYY	OsteoJ	Ila	Ila
PJHXXYY	OsteoJ, OsteoJH	Ila	Ila
PIXXXYY/ZZ	PenBone	Ila	Ila
PIGXXYY/ZZ	Pen-Bone	Ila	Ila
PIPXXYY/ZZ	PenBone Blu	Ila	Ila
PJTXXYY	PickUp	Ila	Ila
PJTHXXYY	PickUp, Pick-Up	Ila	Ila
PJTDXXYY	PickUpD	Ila	Ila
PJK2XXYY	JamBlu	Ila	Ila
PJK2HXXYY	JamBlu	Ila	Ila
PSXXYY	PressTo	Ila	Ila
PSH1D2XXYY	CellColt	Ila	Ila
PJEXXXYY	Harvest	Ila	Ila
PIEXXXYY/ZZ	PenBoneE	Ila	Ila



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Kod produktu medycznego	Nazwa handlowa	MDD 93/42/CEE Klasa ryzyka	NDR 2017/745 Klasa ryzyka
PILEXXYY/ZZ	IllyE	Ila	Ila
PC0XXYY	EasyCut	Ila	Ila
PCXXYY	EasyLock	Ila	Ila
PMXXYY	HandCut	Ila	Ila
PAXXXY	EpaSet	Ila	Ila
VEXXYY	MDCut E, FastCutE	Ila	Ila
VESXXYY	FastCutS	Ila	Ila
MGXXYY	FastCutM	Ila	Ila
MGPXXYY	MDCut P, FastCutP	Ila	Ila
MGPCXXYY	FastCutP	Ila	Ila
MGK1XXYY	Palium Needle	Ila	Ila
MGCXXYY	Palim Needle Palium Coaxial	Ila	Ila
PDXXXY	LightCut Plus	Ila	Ila
PD0XXYY	SemiCut	Ila	Ila
PD0MRXXYY	SemiCut MRI	Ila	Ila
PD0PPXXYY	SemiCut, SemiCut Coax.		Ila
TYXXYY	Themy	Ila	Ila
TYSXXYY	ThemyS	Ila	Ila
TYSCXXYY	ThemySC	Ila	Ila
TYCXXYY	Themy, ThemyC	Ila	Ila
TYQXXYY	ThemyQ	Ila	Ila
TYQCXXYY	ThemyQC	Ila	Ila
PTXXYY	Intro	Ila	Ila
PTMXXYY	Intro	Ila	Ila
PL	Palium	Ila	Ila
PBXXYY	CytoCut	Ila	Ila
PBMXXYY	CytoCut	Ila	Ila
PBQXXYY	CytoCut	Ila	Ila
PBUXXXY	Amnio	Ila	Ila
PBUTXXYY	ChorionSet	Ila	Ila
PEFXXYY	Franseen	Ila	Ila
PEWXXYY	Wescott	Ila	Ila
AETNXXYYY	StimyEcho	Ila	Ila
AETNFXXYYY	StimyEcho	Ila	Ila
AEQNXXYYY	StimyEcho	Ila	Ila
AEQNFXXYYY	StimyEcho	Ila	Ila
AEYNXXYYY	StimyEcho	Ila	Ila
AEYNFXXYYY	StimyEcho	Ila	Ila



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Kod produktu medycznego	Nazwa handlowa	MDD 93/42/CEE Klasa ryzyka	NDR 2017/745 Klasa ryzyka
AETMNXXXXY	StimyEcho16	Ila	Ila
AETMNXXXXY	StimyEcho20	Ila	Ila
AEQMNXXXXY	StimyEcho30	Ila	Ila
AETHXXXXY	StimyPlus	Ila	Ila
AETHFXXXXY	StimyPlus	Ila	Ila
AETMXXXXY	StimyPlus16	Ila	Ila
AEYMXXXXY	StimyPlus20	Ila	Ila
AEQMXXXXY	StimyPlus30	Ila	Ila
AEQHXXXXY	StimyPlus	Ila	Ila
AEQHFXXXXXY	StimyPlus	Ila	Ila
AEYHXXXXY	StimyPlus	Ila	Ila
AEYHFXXXXY	StimyPlus	Ila	Ila
AETRXXXXY	StimyUltra StimyUltra16	Ila	Ila
AETRFXXXXY	StimyUltra	Ila	Ila
AEQRXXXXY	StimyUltra StimyUltra30	Ila	Ila
AEQRFXXXXY	StimyUltra	Ila	Ila
AEYRXXXXY	StimyUltra StimyUltra20	Ila	Ila
AEYRXXXXY	StimyUltra	Ila	Ila
AEYMVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQMVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYHVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQHVXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYMVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQMVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AETHVFXXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEQHVFXXXXY	VygoPlex ENS & Echo	Ila	Ila
AEYMNVXXXXY	VygoPlex Echo	Ila	Ila
AEQMNVXXXXY	VygoPlex Echo	Ila	Ila
AEYNVXXXXY	VygoPlex Echo	Ila	Ila
AEQNVXXXXY	VygoPlex Echo	Ila	Ila
AEYMNVFXXXXXY	VygoPlex Echo	Ila	Ila
AEQMNVFXXXXXY	VygoPlex Echo	Ila	Ila
AEYNVFXXXXXY	VygoPlex Echo	Ila	Ila
AEQNVFXXXXXY	VygoPlex Echo	Ila	Ila
PNXXXXY	Mark	Ila	Ila
PNXXXXY	MarkX	Ila	Ila



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Kod produktu medycznego	Nazwa handlowa	MDD 93/42/CEE Klasa ryzyka	NDR 2017/745 Klasa ryzyka
PNZXXYY	MarkZ	Ila	Ila
PNSXXYY	MarkSlim	Ila	Ila
PNAXXXYY	AutoMark	Ila	Ila
PNAXXXYY	AutoMarkX	Ila	Ila
PRXXYY	RepoMark	Ila	Ila
PRDXXYY	RepoMarkD	Ila	Ila
AVAXXXYY	VeressA	Ila	Ila
AVAQXXYY	VeressQ	Ila	Ila
AVBXXYY	VeressB	Ila	Ila
AVBQXXYY	VeressQ	Ila	Ila
AVCXXYY	VeressC	Ila	Ila
AVCQXXYY	VeressQ	Ila	Ila
AV01TXX	ToraSet	Ila	Ila
AV01XXYYA	ToraSet	Ila	Ila
AV01XXYYB	ToraSet	Ila	Ila
AV01XXYYC	ToraSet	Ila	Ila
AV02TXX	ToraSetValve	Ila	Ila
AV02XXYYA	ToraSetValve	Ila	Ila
AV02XXYYB	ToraSetValve	Ila	Ila
AV02XXYYC	ToraSetValve	Ila	Ila
AV01KS	ParaSet	Ila	Ila
AV02KS	ParaSet	Ila	Ila
PZYDXXYY	GalaKitDuo	Ila	Ila
PZXCXXYY	GalaKitDuo	Ila	Ila
RF0MXXYYRZZα	RF Probe IE	Ila	Ila
RFMXXYYRZZα	RF Probe	Ila	Ila
LPXXYYRZ	Lipo	Ila	Ila
LPXXYYZ	Lipo	Ila	Ila

Delebio, 19.12.2023

Podpis  
Marcello Dell'Oca  
Dyrektor Generalny M.D.L. srl