

NOVOMED GROUP and it's subsidiaries GYNEAS and LCH MEDICAL PRODUCTS Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	NOVOMED GROUP LCH MEDICAL PRODUCTS GYNEAS
Manufacturer address and contact details.	<ul style="list-style-type: none"> - Head office 12-14 rue Sarah Bernhardt 92600 Asnières-sur-Seine France - Warehouse 14 r Ferdinand de Lesseps, 95190 Goussainville- FRANCE
Single Registration Number (SRN) (if available)	SRN NOVOMED GROUP: FR-MF-000022240 SRN LCH MEDICAL PRODUCTS: FR-MF-000022238 SRN GYNEAS: FR-MF-000022216

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	GMED (For MD class IIa) ECM (For DM class Is) <input type="checkbox"/> See attached schedule
Notified body number (if applicable)	GMED N° 0459

	ECM N° 1282 <input type="checkbox"/> See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	ECM20MDD16 REV.0 ECM20MDD17 REV.0 CE N° 36980 REV. 1 CE N° 36979 REV. 2 CE N°36982 REV. 1 CE N° 36981 REV. 2 CE N° 36974 REV. 0 CE N° 36973 REV. 1 x See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	For MD class IIa: 10/09/2023 , extended by addendum For MD Class Is: 27/05/2024. x See attached schedule
End date of extended validity/transition period	MD class IIa and Is: 31/12/2028. <input type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (see attached certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

Expired *before* 20 March 2023:

- Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
- A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

- A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

X Expired/expires *after* 20 March 2023:

- X Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

- X A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

➤ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Novomed GROUP

Location & Date : Asnières Sur Seine

Signature, Print Name, Title: Jean- Christophe FERRER

Contact Details (at least email): jcferrer@novomedgroup.com



7^h of May 2024

Schedule of Devices

The above NOVOMED's Declaration is valid for the following devices:

Identification of the device(s) ¹ (e.g., device name, family/group name, device model or catalogue number)	Manufacturer Name (s) (if applicable)	Directive Certificate number(s) to which this confirmation is made (if applicable)	Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the MDR application was lodged/contract signed (if applicable)	End date of extended validity / transition period	Substitute Device(s) (if applicable)
Kit for IUD Insertion	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
IUD kit Gyneas Evolution	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
IUD kit Gyneas Evolution (CHEMIST)	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Evolution double hysteroscope	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Cut clamp forceps	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Long Scissors with Littauer Blades	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Metallic Cheron Forcep	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Cheron forcep	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA

Metallic Bengolea Forcep	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Evolution forceps	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM 1282	KIWA N°0476	31/12/2028	NA
Pozzi Forcep pink	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Pozzi Forcep pink	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Metallic Palmer Pozzi Forcep	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Metallic Pozzi Forcep	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
DIU hook	GYNEAS	ECM20MDD16 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Suture removal kits	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Magill forceps - straight - 170mm Magill forceps - straight - 200mm Magill forceps - straight - 250mm	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Metallic staple removers	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Dressing Kit	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Anatomical forcep	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Kocher forcep	LCH MEDICAL	ECM20MDD17 rev.0	27/05/2024	ECM N°1282	KIWA N°0476	31/12/2028	NA
Disposable sterile Kits for Cut skin	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Scissors	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Mayo Dissecting Scissors	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Metzenbaum Dissecting Scissors	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA

Iridectomy scissors	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Straight and sharpened Operating Scissor	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Straight and curved Operating Scissor	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Stevens thin curved scissors	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Thin Dissecting forcep	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Adson micro forcep	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Micro Adson Dissecting Forcep without tooth	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Ultra thin Dissecting Adson Forcep with tooth	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Ultra thin Dissecting Adson Forcep without tooth	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit For Suture Precisio 1'	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit For Suture "Precision"	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Micro Halsey Type Needle Holder	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Set de pose de suture "	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Set de suture	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Set de suture	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Set de pose de suture	NOVOMED GROUP	n° 36980 rev. 1+ n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA

Set de suture	NOVOMED GROUP	n° 36980 rev. 1+n° 36979 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit for Hypodermic Implant Insertion	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit for Hypodermic Implant Insertion - Pharmacy	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
kits for removal of contraceptive implant	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit for hypodermic implant removal Extrimplant kit (for chemist)	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Kit for hypodermic implant removal Extrimplant kit	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
sterile kits for removal of contraceptive implant	NOVOMED GROUP	N°36982 rev. 1+n° 36981 rev. 2	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Gyn&Cube pessary SMALL	NOVOMED GROUP	CE n° 36974 rev. 0+ n° 36973 rev. 1	10/09/2023	GMED N°0459	KIWA N°0476	31/12/2028	NA
Gyn&Cube pessary STANDARD	NOVOMED GROUP	CE n° 36974 rev. 0+ n° 36973 rev. 1	10/09/2023	GMED N°0459	Kiwa N°0476	31/12/2028	NA
Gyn&Cube pessary LARGE	NOVOMED GROUP	CE n° 36974 rev. 0+ n° 36973 rev. 1	10/09/2023	GMED N°0459	Kiwa N°0476	31/12/2028	NA

