DISTRIBUTION QUALITY AGREEMENT FOR MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES IN EUROPE

Warehousing and Distribution Quality Agreement
dated *2023* **between** *Sanofi s.r.l & Opella Healthcare s.r.l.* **and** *customers*

Between:

CONTRACT GIVER *Sanofi S.r.l & Opella Healthcare s.r.l* whose registered office is at *viale Bodio 37/b - 20158 Milano*

And:

CONTRACT ACCEPTOR ***(****Hospitals, private clinics, pharmacies, CAD, ASL,wholesalers)* which is represented by the Responsible Person (or equivalent function)

CONTRACT GIVER and **CONTRACT ACCEPTOR** are hereafter referred to as "the **Parties**".

WHEREAS, **CONTRACT GIVER** has entrusted **CONTRACT ACCEPTOR**, with the distribution of the Product(s) for the *Italian* market, which **CONTRACT ACCEPTOR** accepts.

WHEREAS **CONTRACT GIVER** is acting as Distributor of Medical Devices (MD) and In Vitro Diagnostic Medical Devices (IVD), hereafter called Devices for the *Italian* market.
The term “device” is used hereafter to collectively refer to the applicable product scope.
WHEREAS **CONTRACT GIVER** is responsible for the compliance with all applicable regulatory legal requirements to fulfill its obligations under the European Union Medical Device Regulation 2017/745 and the European Union In Vitro Diagnostic Medical Devices Regulation 2017/746 referring to its Distributor role.

WHEREAS **CONTRACT ACCEPTOR** is acting as Distributor due to definition reported in the applicable Regulation: “**Distributor’** *means any natural or legal person in the supply chain, other than the legal manufacturer or the importer, that makes a device available on the market, up until the point of putting into service*”

The purpose of this Agreement is to cover additional services requested to the **CONTRACT ACCEPTOR** considering the implementation of the European Union Medical Device Regulation 2017/745 (EU MDR) and of the European Union In Vitro Diagnostic Medical Devices Regulation 2017/746 (EU IVDR).

Now therefore **the Parties** agree as follows:

ARTICLE 1: Operations

Devices Verifications:

CONTRACT ACCEPTOR shall implement verifications on Devices as per **CONTRACT GIVER** instructions. The list of Devices in scope is provided and updated by the **CONTRACT GIVER** (Appendix 1).

CONTRACT ACCEPTOR shall check one unit of each incoming batch of Devices prior to making the Device batch available on the market (saleable stock). The frequency and quantity can be reassessed and based on own risk assessment.

CONTRACT ACCEPTOR shall check the following against information provided by *Sanofi or Opella Healthcare* prior to making the Device available on the market:

- The Device has been CE marked – physical check of the CE marking
- The declaration of conformity (DoC) of the Device has been drawn up.

  Note: For Medical Devices compliant with directive 93/42/EEC (MDD) and In Vitro Diagnostic Medical Devices compliant with directive 98/79/EC (IVDD), Declaration of Conformity are valid until the end of the period

indicated on the DoC - transition periods for devices compliant with MDD/IVDD shall be checked (latest date May 2024 for Medical Devices).

- If applicable, presence of Instruction for Use (IFU) and labeling in the local language(s) of the Member States to which the Product will be supplied
- The name, registered place of business and address of the legal manufacturer is identified on the device or its packaging
- For Products imported from outside the European Union, the name, registered place of business and address of the importer is identified visibly on the Device or on its packaging or in a document accompanying the Device. Any additional label does not obscure any information on the label provided by the legal manufacturer.
- Where applicable, a Unique Device Identifier (UDI) has been assigned by the legal manufacturer to the Device and its packaging in accordance with applicable requirements.

  *Note: For class III implantable Medical Devices and where applicable, **CONTRACT ACCEPTOR** shall store and keep, preferably by electronic means, the UDI of the Medical Devices which they have supplied or with which they have been supplied.*

CONTRACT GIVER shall provide the **CONTRACT ACCEPTOR** with the necessary information to perform the checks defined (DoC, importer details where applicable, copy of the IFU and labeling).

CONTRACT ACCEPTOR shall document the checks performed

Non-conformities:

In the event a non-conformity to EU MDR, IVDR is identified during the checks performed, **CONTRACT ACCEPTOR** shall immediately and no later than 1 (one) business day after the checks, inform in writing the **CONTRACT GIVER.** The completed Device checking form must be sent to **CONTRACT GIVER** with a description of the identified non-conformity.

CONTRACT ACCEPTOR shall quarantine the non-conforming Devices until receiving written communication from the **CONTRACT GIVER** that the Device can be made available to the market.

CONTRACT GIVER shall provide the decision on Product's disposition.

CONTRACT GIVER shall communicate any further necessary actions to the **CONTRACT ACCEPTOR** for non-conforming devices.

In case **CONTRACT GIVER** is informed of a non-conformity to EU MDR/IVDR, **CONTRACT GIVER** shall inform in writing **CONTRACT ACCEPTOR** and provide its instruction for further handling of the concerned Device.

Changes and Modifications

CONTRACT ACCEPTOR must not perform any of the following changes:

- Over-labelling and branding a device with their own name, trade name or trademark
- Changing the intended purpose of a device
- Modifying a device in such a way that compliance with the applicable regulatory requirements may be affected
- translate the information supplied by the manufacturer or of further information which is necessary in order to market the device in the relevant Member State
- change the outer packaging of a device already placed on the market , including a change of pack size

Remark: If distributors perform any of the above, they assume the obligation of the legal manufacturer as define on Art 18 of regulation

Storage & Storage Conditions

CONTRACT ACCEPTOR shall ensure that the Device are stored safely.

CONTRACT ACCEPTOR shall restrict the access to the Device to identified authorized personnel.

CONTRACT ACCEPTOR shall, at all times, ensure that the Device are stored in a clean environment: storage areas must be suitably cleaned and maintained according to a written program, in order to prevent the build up of obsolete material and dirt.

All the Device will be stored protecting them from light and at the range temperature indicated in Appendix 1.

Receipt, warehousing of the Device

Device Traceability: all entities in the supply chain should be traceable. There should be written procedures and records, including distribution records, to ensure traceability of the Device distributed. Possible deviations detected at reception, including temperature deviations during transport, shall be notified to ***CONTRACT GIVER*** as described in section "Deviations, Corrective and Preventive Actions".

Shipment Device

Device should be transported in such a way to maintain the temperature range indicated in the APPENDIX 1 until the arrival and delivery to final customer.

Audit & Self inspection

If needed, ***CONTRACT ACCEPTOR*** shall allow representatives from ***CONTRACT GIVER*** to have access for audit purposes to its related premises and to the associated records.

CONTRACT GIVER shall inform ***CONTRACT ACCEPTOR*** of any planned audit and audit program details by written notice 30 (thirty) Business Days prior to the start date of the audit (except for audit for cause). Where significant quality issues are detected, ***CONTRACT GIVER*** shall be allowed to carry out when needed audits for cause designed to lead to resolution of these issues.

ARTICLE 2: Responsibilities

	Responsibilities - Storage & Distribution	**Contract Giver**	**Contract Acceptor**
	Quality & Compliance		
1	Ensure that "procured" Products to **CONTRACT ACCEPTOR** comply with the regulatory requirements applicable to Medical Devices and In Vitro Diagnostic Medical Devices through quality agreements set-up with upstream economic operators.	X	-
2	Comply with all applicable regulatory legal requirements to fulfill its obligations under the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 referring to its role as a distributor.	X	X
	Personnel		
3	Ensure that the personnel involved in the handling of Products have the appropriate qualification to handle the checks requested on Devices.	-	X
	Verifications for Devices		
4	Provide **CONTRACT ACCEPTOR** with sufficient information to carry out the required verification checks.	X	-
5	Implement verifications on Devices as per **CONTRACT GIVER** instructions (see Article 1).	-	X
6	Document the checks performed as agreed with **CONTRACT GIVER.**	-	X

	Responsibilities - Storage & Distribution	**Contract Giver**	**Contract Acceptor**
	Documentation		
7	Retain all documentation related to verifications performed on Devices and the Devices traceability for a period of ten (10) years - and fifteen (15) years for implantable Medical Devices - after the last device covered by the EU declaration of conformity has been placed on the market. This includes: - Any health institution or healthcare professional to which they have directly supplied a Device - Any other economic operator (wholesalers, pharmacies) to whom they have directly supplied a Device - Any economic operator (Sanofi and Opella Healthcare entity) who has directly supplied them with a Device - Records of checks carried out and the approval of devices into saleable stock.	-	X
8	For class III implantable Medical Devices and where applicable, store and keep, preferably by electronic means, the UDI of the Medical Devices which they have supplied or with which they have been supplied.	-	X
9	Keep this documentation at disposal of the **CONTRACT GIVER** and of the Competent Authorities.	-	X
10	Provide this documentation to **CONTRACT GIVER** within 1 business days after they receive a request.	-	X
	Storage and Distribution		
11	Ensure, whilst the Device is stored in their warehouse and distributed downstream, storage or transport conditions comply with the conditions set by the legal manufacturer where available.	-	X
	Access to Devices		
12	Upon request of **CONTRACT GIVER**, provide free samples or, where that is impracticable, grant access to the Device to competent authorities.	-	X
13	Inform the **CONTRACT GIVER** in case of request received from competent authorities.	-	X
14	Provide their instructions to the **CONTRACT ACCEPTOR** in case of request received from competent authorities**.**	X	-
	Non-conforming Devices, complaints, returns, suspected falsified products and product recalls		
15	In the event a non-conformity to EU MDR/IVDR is identified during the checks performed, inform in writing the **CONTRACT GIVER** immediately and no later than 1 business day after the checks**.**	-	X
16	Quarantine the non-conforming Devices until receiving written decision on Product's disposition from the **CONTRACT GIVER.**	-	X
17	Communicate in writing the decision on Product's disposition and any further necessary actions to the **CONTRACT ACCEPTOR** for non-conforming Devices.	X	-
18	In case informed of a non-conformity to EU MDR/IVDR, inform in writing **CONTRACT ACCEPTOR** and provide its instruction for further handling of the concerned Device.	X	-
19	Forward to **CONTRACT GIVER** immediately and no later than 1 (one) business day, any information they may receive related to complaints, suspected incidents related to a Device, information indicating that the Device presents serious risk, information indicating that the Device is not compliant with the regulatory requirements, suspected falsified Device.	-	X

	Responsibilities - Storage & Distribution	Contract Giver	Contract Acceptor
	Outsourced activities		
20	If any activities are outsourced, provisions to ensure that the sub-contractors are appropriately controlled and that written agreements between distributor and sub-contractor are established which include relevant requirements and provisions		X

ARTICLE 3:

All of the terms and conditions stated in the Quality Agreement have been accepted and shall remain in full force and effect until the next review.

DEFINITIONS in the context of the European Union Medical Device Regulation 2017/745 (EU MDR) and the European Union In Vitro Diagnostic Medical Devices Regulation 2017/746 (EU IVDR).

'CE marking of conformity' or **'CE marking'** means a marking by which a legal manufacturer indicates that a device is in conformity with the applicable requirements set out in the EU MDR or the EU IVDR and other applicable European Union harmonization legislation providing for its affixing

'Distributor' means any natural or legal person in the supply chain, other than the legal manufacturer or the importer, that makes a device available on the market, up until the point of putting into service

'Falsified device' means any device with a false presentation of its identity, of its source or of its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights

'Fulfilment service provider' means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council (31), parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council (32), and any other postal services or freight transport services;

'**Importer'** means any natural or legal person established within the European Union that places a device from a third country on the European Union market

'Label' means the written, printed or graphic information appearing either on the device itself, or on the packaging of each unit or on the packaging of multiple devices

'**Instructions for use**' means the information provided by the legal manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken

'Making available on the market' means any supply of a device, other than an investigational medical device and other than a device for performance study, for distribution, consumption or use on the European Union market in the course of a commercial activity, whether in return for payment or free of charge

'**Legal Manufacturer'** means a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

'Placing on the market' means the first making available of a device, other than an investigational medical device and other than a device for performance study, on the European Union market

'Putting into service' means the stage at which a device, other than an investigational medical device and other than a device for performance study, has been made available to the final user as being ready for use on the European Union market for the first time for its intended purpose

'Serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat

APPENDIX 1: List of Devices sold by sanofi and Opella Healthcare

APPENDIX 2: Items to be included in the Device verification form

Version	Approval Date (year/month/day)	Summary of Changes
01	June 2023	First edition
02	Sept 2023	Opella Heathcare included

Contact list:

SANOFI

Position	*Address*	*Phone & Mail*
Incidents	SANOFI S.r.l. Viale Bodio 37/B 20158 Milano - ITALY	farmacovigilanza.italia@sanofi.com
Complaint (PTC)	SANOFI S.r.l. Viale Bodio 37/B 20158 Milano - ITALY	Italy_AQO@sanofi.com
Medical Information	SANOFI S.r.l. Viale Bodio 37/B 20158 Milano - ITALY	informazioni.medicoscientifiche@sanofi.com

Opella Healthcare

Position	***Address***	***Phone & Mail***
Incidents	Opella Healthcare srl Viale Bodio 37/B 20158 Milano - ITALY	VigilanzaCHC.ITA@sanofi.com
Complaint (PTC)	Opella Healthcare srl Viale Bodio 37/B 20158 Milano - ITALY	CHCIT-Quality@sanofi.com
Medical Information	Opella Healthcare srl Viale Bodio 37/B 20158 Milano - ITALY	informazionimedicoscientifiche.chc@sanofi.com

APPENDIX 1

List of Medical Devices, their Legal Manufacturer, Importer & associated storage conditions distributed by Sanofi

GMID	Device designation	UDI (when applicable)	Legal Manufacturer	Importer	Classification	Storage conditions
00755189	ALLSTAR PRO BLU	N.A.	Sanofi-Aventis Deutschland GmbH Industriepark Hochst- D-65926 Frankfurt am Main-Germania	N.A.	IIb	N.A.
00755214	ALLSTAR PRO SILVER	N.A.	Sanofi-Aventis Deutschland GmbH Industriepark Hochst- D-65926 Frankfurt am Main-Germania	N.A.	IIb	N.A.
00361684	BGSTAR 25 strisce reattive	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	MDSS GMBH Schiffgraben 41 30175 Hannover, Germania (MANDATARIO)	IVD	Not above 30°C and not below 8°C.
00357196	BGSTAR 50 strisce reattive	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	MDSS GMBH Schiffgraben 41 30175 Hannover, Germania (MANDATARIO)	IVD	Not above 30°C and not below 8°C.
00513625	BGSTAR soluzione controllo concentraz. alta	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	MDSS GMBH Schiffgraben 41 30175 Hannover, Germania (MANDATARIO)	IVD	Not above 30°C and not below 2°C. Do not refrigerate.
00596710	BGSTAR soluzione di controllo concentraz. normale	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	MDSS GMBH Schiffgraben 41 30175 Hannover, Germania	IVD	Not above 30°C and not below 2°C. Do not refrigerate.
00472793	JUNIORSTAR BLU	N.A.	Haselmeier GmbH Vaihinger Straße 48 70567 Stuttgart Germania	N.A.	IIb	N.A.
00472799	JUNIORSTAR SILVER	N.A.	Haselmeier GmbH Vaihinger Straße 48 70567 Stuttgart Germania	N.A.	IIb	N.A.
00507909	MYSTAR 25 LANCETTE- ago 28"	N.A.	HTL-Strefa S.A. Ul. Adamòwek 7 95-035 Ozorkòw Polonia	N.A.	IIa	N.A.

00507938	MYSTAR 25 LANCETTE- ago 33”	N.A.	HTL-Strefa S.A. Ul. Adamòwek 7 95-035 Ozorkòw Polonia	N.A.	IIa	N.A.
00505673	MYSTAR 50 LANCETTE- ago 28"	N.A.	HTL-Strefa S.A. Ul. Adamòwek 7 95-035 Ozorkòw Polonia	N.A.	IIa	N.A.
00505677	MYSTAR 50 LANCETTE- ago 33"	N.A.	HTL-Strefa S.A. Ul. Adamòwek 7 95-035 Ozorkòw Polonia	N.A.	IIa	N.A.
00505197	MYSTAR EXTRA	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	MDSS GMBH Schiffgraben 41 30175 Hannover, Germania	IVD	N.A.
00635567	MYSTAR PLUS	N.A.	AGAMATRIX, Inc. 7C Raymond Avenue, Salem, NH 03079 U.S.A.	DSS GMBH Schiffgraben 41 30175 Hannover, Germania	IVD	N.A.
00505681	MYSTAR SILK FEEL	N.A.	HTL-Strefa S.A. Ul. Adamòwek 7 95-035 Ozorkòw Polonia	N.A.	IIa	Room temperature, away from light and heat sources.
00736315	SYNVISC HIP 2 ml 1 syringe	N.A.	GENZYME BIOSURGERY 1125 Pleasant View Terrace Ridgefield, NJ 07657 U.S.A.	GENZYME BV Paasheuvelweg 25, 1105BP Amsterdam, The Nederlands	III	Not above 30°C and not below 2°C. Do not refrigerate.
00736311	SYNVISC KNEE 2 ml 3 syringes	N.A.	GENZYME BIOSURGERY 1125 Pleasant View Terrace Ridgefield, NJ 07657 U.S.A.	GENZYME BV Paasheuvelweg 25, 1105BP Amsterdam, The Nederlands	III	Not above 30°C and not below 2°C. Do not refrigerate.
00736303	SYNVISC ONE 6 ml 1 syringe	N.A.	GENZYME BIOSURGERY 1125 Pleasant View Terrace Ridgefield, NJ 07657 U.S.A.	GENZYME EUROPE BV Paasheuvelweg 25, 1105BP Amsterdam, Olanda	III	Not above 30°C and not below 2°C. Do not refrigerate.

GMID	Device designation	UDI (when applicable)	Legal Manufacturer	Importer	Classification	Storage conditions
00724333	AGO BD Eclipse - Luer Slip 25G x 1 H	N.A.	Becton Dickinson S.A.U Cra.Mequinenzas/n. 22520 -Fraga (Huesca) Spain	N.A.	IIa	N.A.
00739368	AGO BD Eclipse - Luer Slip 25G x 5/8 H	N.A.	Becton Dickinson S.A.U Cra.Mequinenzas/n. 22520 -Fraga (Huesca) Spain	N.A.	IIa	N.A.
00739926	AGO BD Microlance - 25G 1 25mm	N.A.	Becton Dickinson S.A.U Cra.Mequinenzas/n. 22520 -Fraga (Huesca) Spain	N.A.	IIa	N.A.
00739927	Ago BD Microlance 25G 5/8 16mm	N.A.	Becton Dickinson S.A.U Cra.Mequinenzas/n. 22520 -Fraga (Huesca) Spain.	N.A.	IIa	N.A.
00803975	BD Plastipak LL Syringe 1 ML	N.A.	BD Medical – Route 7 and Grace way - CT 06018 CANAAN site US / Importer Eysins In Europe	N.A.	IIa	N.A.
00793847	Safety Hypodermic needle Surguard 3: 25G x 1: confezioni da 100	N.A.	TERUMO (PHILIPPINES) CORPORATION- 124 East Main Ave., Laguna Technopark, Binan City, Laguna, Philippines	N.A.	IIa	N.A.
00793849	Hypodermic Needle 25Gx1: confezioni da 5000	N.A.	TERUMO (PHILIPPINES) CORPORATION- 124 East Main Ave., Laguna Technopark, Binan City, Laguna, Philippines	N.A.	IIa	N.A.
00803977	Neolus TERUMO	N.A.	TERUMO (PHILIPPINES) CORPORATION- 124 East Main Ave., Laguna Technopark, Binan City, Laguna, Philippines	N.A.	IIa	N.A.
00821443	KIT: 2 needles G25 x 1 and one 2,5 ml Luer Slip syringe	N.A.	Pickdare- Pikdare S.p.A. via Saldarini Catelli, 10 – 22070 Casnate con Bernate (CO) Italy	N.A.	IIa	N.A.

List of Medical Devices, their Legal Manufacturer, Importer & associated storage conditions distributed by Opella Healthcare

GMID	Device designation	UDI (when applicable)	Legal Manufacturer	Importer	Classification	Storage conditions
745917	BISOLVON DUO POCKET LENITIVO 14 STICKPACK CP	N.A.	Labomar S.r.l. - Via N. Sauro 35, Istrana, TV (Italia)	N.A.	IIa	Room temperature in a cool, dry place
792582	BISOLVONDUO SCIR MIELE 100 ML CP	N.A.	Hälsa Pharma GmbH – Maria-Goeppert-Str. 5, D-23562 Lübeck (Germania)	N.A.	IIa	Not above 25°C. Do not refrigerate.
874019	BISOLVON PHYTOXIL 12 STICK PACK CP	N.A.	Labomar S.r.l. - Via N. Sauro 35, Istrana, TV (Italia)	N.A.	IIa	Room temperature in a cool, dry place
655302	DULCOSOFT 1 FLAC 250 ML CP	N.A.	Hälsa Pharma GmbH – Maria-Goeppert-Str. 5, D-23562 Lübeck (Germania)	N.A.	IIb	Not above 25°C. Do not refrigerate
756817	DULCOSOFT GRANULATO 10 GR 20 BST NEW CP	N.A.	Fairpharm Vertriebs GmbH – Am Krebsenbach 5-7, D-83670 Bad Heilbrunn (Germania)	N.A.	IIb	Not above 25°C. Do not refrigerate.
837645	DULCOSOFT GRANULATO 10 GR 28 BST EC	N.A.	Fairpharm Vertriebs GmbH – Am Krebsenbach 5-7, D-83670 Bad Heilbrunn (Germania)	N.A.	IIb	Not above 25°C. Do not refrigerate.
778714	DULCOSOFT IRREGOLARITA' GONFIORE 200 G CP	N.A.	Biofarma – Via Castelliere 2 – Mereto di Tomba (UD) - Italia	N.A.	IIa	Cool and dry place, away from light and heat sources.
838054	DULCOSOFT IRREGOLARITA GONFIORE 4 BST SAGGIO	N.A.	Biofarma – Via Castelliere 2 – Mereto di Tomba (UD) - Italia	N.A.	IIa	Cool and dry place, away from light and heat sources.
881333	DULCOSOFT GRANULATO 10 GR 4 BST SAGGIO	N.A.	Fairpharm Vertriebs GmbH – Am Krebsenbach 5-7, D-83670 Bad Heilbrunn (Germania)	N.A.	IIb	Not above 25°C. Do not refrigerate.
694025	MAALOX RRAPID 20 STICK CP NF	N.A.	Biofarma S.r.l - Via Castelliere, 2 - 33036 Mereto di Tomba, UD (Italia)	N.A.	IIa	Not above 25°C and not below 8°C, protected from light and away from heat sources. Do not refrigerate.

836982	MAALOX REFLURAPID 28 BST EC	N.A.	Biofarma S.r.l - Via Castelliere, 2 - 33036 Mereto di Tomba, UD (Italia)	N.A.	IIa	Not above 25°C and not below 8°C, protected from light and away from heat sources. Do not refrigerate
601992	MAALOX RRAPID TABS 40 CPR CP	N.A.	Biofarma S.r.l - Via Castelliere, 2 - 33036 Mereto di Tomba, UD (Italia)	N.A.	IIa	Not above 25°C and not below 8°C, in a dry place, protected from light and away from heat sources
878404	INITIV 3 PATCHES INFRAROSSO COLLO CP	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
878406	INITIV 3 PATCHES INFRAROSSO SCHIENA CP	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
878403	INITIV 3 PATCHES INFRAROSSO SPALLE CP	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
878443	INITIV 4 PATCHES INFRAROSSO SCHIENA	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
878445	INITIV 4 PATCHES INFRAROSSO SPALLE	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
878438	INITIV 4 PATCHES INFRAROSSO COLLO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
888784	INITIV 1 PATCH INFRAROSSO SCHIENA SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
893305	INITIV 1 PATCH SCHIENA FED. ATLETICA SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
893304	INITIV 1 PATCH SPALLE FED. ATLETICA SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
893303	INITIV 1 PATCH COLLO FED. ATLETICA SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.

893588	INITIV 6 PATCHES SCHIENA "BANDIERA"	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
894423	INITIV 1 PATCH SCHIENA "BANDIERA" SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
894425	INITIV 1 PATCH COLLO "BANDIERA" SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.
894426	INITIV 1 PATCH SPALLE "BANDIERA" SAGGIO	N.A.	Eurosirel S.P.A. – Viale Europa, 30 – 20047 Cusago, MI (Italia)	N.A.	I	Room temperature, in a dry place, protected from light.

APPENDIX 2

Items that should be included in the Device verification (only for example)

Information related to the Device:

Device Name and Presentation
GMID
Batch number
Expiry date
Purchase Order number / delivery note
Number of samples taken for verification:

Verifications:

- ☐ Valid EU Declaration of conformity
- ☐ CE marking on the device and its packaging
- ☐ Presence of instruction for use (IFU) in the language(s) of the country/member state where the device will be made available.
- ☐ Batch number / Expiry date
- ☐ Name and address of the legal manufacturer on the device and its packaging
- ☐ Name and address of the importer if applicable (for devices imported) on the device or packaging or accompanying documentation.
- ☐ UDI, when available
- ☐ Class III implantable - the UDI of the devices received have been stored.

Name and Job title of the person performing the checks
Date and signature

Conclusion on the checks:

Conclusion on the compliance of the device.
Non-conformity description if any

Date and Signature by the Third-Party Logistics responsible person or equivalent function/delegate.

1. SIGNATURES

IN WITNESS WHEREOF, this Quality Agreement has been accepted and signed

For and on behalf of Sanofi s.r.l

Writer & Reviewer*

Name: Daniela Damato

Job Title: Quality Head Italy&Malta

Date and signature:

Daniela Damato

Electronically signed by: Daniela DAMATO
Reason: signed
Date: Sep 12, 2023 15:50 GMT+2

For and on behalf of Opella Healthcare s.r.l

Writer & Reviewer*

Name: Maria Rita Castiglione

Job Title: Country Quality Manager Italy

Date and signature:

MariaRita CASTIGLIONE

Electronically signed by: MariaRita CASTIGLIONE
Reason: approval
Date: Sep 12, 2023 17:48 GMT+2