Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- 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	CHIRANA T. Injecta, s.r.o.
Manufacturer address and contact details	Komoranska 2148, 143 00 Prague 4, Czech Republic
Single Registration Number (SRN) (if available)	CZ-MF-000034353

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

Notified body name (if applicable)	☒See attached schedule
Notified body number (if applicable)	☒See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Directive Certificate number(s) to which this confirmation is made (if applicable)	☒See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒See attached schedule
End date of extended validity/transition period	☒See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- 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.

  Choose applicable statements:

  ☐ 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

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

CHIRANA T. Injecta, s.r.o.
Komořanská 2148 • 143 00 Praha 4 • Czech Republic
Tel.: +420 241 768 407 • Fax: +420 244 400 910 • E-mail: info@t-injecta.cz • www.t-injecta.cz
IČO: 26216469 • DIČ: CZ26216469 • Reg.: Městský soud v Praze C/233080

☐ 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)

Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

☐ 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.

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ 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.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ 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 substitutes 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:

☒ 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 AIMDD or 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:

CHIRANA T. Injecta, s.r.o.

Komoranska 2148, 143 00 Prague 4, Czech Republic

4.3. 2024

CHIRANA T. Injecta, s.r.o.
14
Komořanská 2148
143 00 Praha 4
IČO: 26216469 DIČ: CZ26216469

RNDr. Anar Mamytbekova

Person responsible for regulatory compliance

E-mail: anar.mamytbekova@t-injecta.cz

Phone: + 420 241 097 902, + 420 731 540 982

Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**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)
Surgical suture Trade name: Chirasorb braided UDI-DI: 8596165ChirasorbV5	**MED 190018 MED 190021**	**26.05.2024**	**Electrotechnical Testing Institute, s.p., 1014**	**3EC International a. s., 2265**	**31.12.2027**	**N/A**
Surgical suture Trade name: Chirasorb rapid braided UDI-DI: 8596165ChirasorbrapidNS	**MED 190018 MED 190022**	**26.05.2024**	**Electrotechnical Testing Institute, s.p., 1014**	**3EC International a. s., 2265**	**31.12.2027**	**N/A**
Surgical suture Trade name: Chirasorb Plus braided UDI-DI: 8596165ChirasorbPlusBQ	**MED 190018 MED 190027**	**26.05.2024**	**Electrotechnical Testing Institute, s.p., 1014**	**3EC International a. s., 2265**	**31.12.2027**	**N/A**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Surgical suture Trade name: Chirlac braided Alternative trade name: C-TEC Alfatec braided UDI-DI: 8596165ChirlacA8	MED 190018 MED 190019	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Surgical suture Trade name: Chirlac rapid braided UDI-DI: 8596165Chirlacrapid5R	MED 190018 MED 190020	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Surgical suture Trade name: Monolac monofilament Alternative trade name: C-TEC Caprotec monofilament UDI-DI: 8596165MonolacKF	MED 190018 MED 190024	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Surgical suture Trade name: Polydox monofilament Alternative trade name: C-TEC Cynadox monofilament UDI-DI: 8596165PolydoxPW	MED 190018 MED 190023	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Surgical suture Trade name: Chiralen monofilament UDI-DI: 8596165ChiralenXB	MED 190018 MED 190025	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A

CHIRANA T. Injecta, s.r.o.
Komořanská 2148 • 143 00 Praha 4 • Czech Republic
Tel.: +420 241 768 407 • Fax: +420 244 400 910 • E-mail: info@t-injecta.cz • www.t-injecta.cz

Surgical mesh – partially absorbable Trade name: Capromesh UDI-DI: 8596165CapromeshX4	MED 190018 MED 190026	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Non-absorbable surgical mesh Trade name: Chiralen mesh UDI-DI: 8596165ChiralenMeshYL	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2027	N/A
Surgical suture Trade name: Silon braided UDI-DI: 8596165SilonbraidedT9	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A
Surgical suture Trade name: Silon monofilament Alternative trade name: C-TEC Celon monofilament UDI-DI: 8596165Silonmonofil6X	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A
Surgical suture Trade name: Tervalon braided UDI-DI: 8596165TervalonDV	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A
Surgical suture Trade name: Silk braided UDI-DI: 8596165SilkN4	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A
Surgical suture Trade name: Chiraflon monofilament UDI-DI: 8596165ChiraflonSA	MED 190017	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A
Eyed needles – non-sterile Trade name: Eye-needles UDI-DI: 8596165EyeNeedlesSU	MED 200068	26.05.2024	Electrotechnical Testing Institute, s.p., 1014	3EC International a. s., 2265	31.12.2028	N/A

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CHIRANA T. Injecta, s.r.o.
Komořanská 2148, Modřany,
143 00 Praha 4,
Czech Republic

Attn. Marcin Sieczek, PaedDr. Marie Bakova / Executive Managers

Our reference	*Contact person*	BRATISLAVA
MIT/2024/P040	Michal Tomin / +421 915 366 774	29.2.2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as amended as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **3EC International a.s.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2265 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

CHIRANA T. Injecta, s.r.o.
Komořanská 2148, Modřany,
143 00 Praha 4,
Czech Republic

SRN Number (if available): CZ-MF-000034353

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Katarína Tomin Srdošová, PhD.
Director of NB2265

3EC International a.s. (4)
Hraničná 18, 821 05 Bratislava
Slovak Republic
ID No.: 36 789 003
VAT No.: SK2022390073

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Surgical suture Trade name: Chirasorb braided UDI-DI: 8596165ChirasorbV5	Class III	N/A	MED 190018; NB1014 MED 190021; NB1014
Surgical suture Trade name: Chirasorb rapid braided UDI-DI: 8596165ChirasorbrapidNS	Class III	N/A	MED 190018; NB1014 MED 190022; NB1014
Surgical suture Trade name: Chirasorb Plus braided UDI-DI: 8596165ChirasorbPlusBQ	Class III	N/A	MED 190018; NB1014 MED 190027; NB1014
Surgical suture Trade name: Chirlac braided Alternative trade name: C-TEC Alfatec braided UDI-DI: 8596165ChirlacA8	Class III	N/A	MED 190018; NB1014 MED 190019; NB1014
Surgical suture Trade name: Chirlac rapid braided UDI-DI: 8596165Chirlacrapid5R	Class III	N/A	MED 190018; NB1014 MED 190020; NB1014
Surgical suture Trade name: Monolac monofilament Alternative trade name: C-TEC Caprotec monofilament	Class III	N/A	MED 190018; NB1014 MED 190024; NB1014

UDI-DI: 8596165MonolacKF			
Surgical suture **Trade name: Polydox monofilament** **Alternative trade name: C-TEC Cynadox monofilament** **UDI-DI: 8596165PolydoxPW**	Class III	N/A	MED 190018; NB1014 MED 190023; NB1014
Surgical suture **Trade name: Chiralen monofilament** **UDI-DI: 8596165ChiralenXB**	Class III	N/A	MED 190018; NB1014 MED 190025; NB1014
Surgical mesh – partially absorbable **Trade name: Capromesh** **UDI-DI: 8596165CapromeshX4**	Class III	N/A	MED 190018; NB1014 MED 190026; NB1014
Non-absorbable surgical mesh **Trade name: Chiralen mesh** **UDI-DI: 8596165ChiralenMeshYL**	Class III	N/A	MED 190017; NB1014
Surgical suture **Trade name: Silon braided** **UDI-DI: 8596165SilonbraidedT9**	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190017; NB1014
Surgical suture **Trade name: Silon monofilament** **Alternative trade name: C-TEC Celon monofilament** **UDI-DI: 8596165Silonmonofil6X**	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190017; NB1014
Surgical suture **Trade name: Tervalon braided** **UDI-DI: 8596165TervalonDV**	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190017; NB1014
Surgical suture **Trade name: Silk braided** **UDI-DI: 8596165SilkN4**	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190017; NB1014
Surgical suture **Trade name: Chiraflon monofilament** **UDI-DI: 8596165ChiraflonSA**	Class IIb excluding Class IIb implantable non-WET	N/A	MED 190017; NB1014
Eyed needles - non-sterile **Trade name: Eye-needles** **UDI-DI: 8596165EyeNeedlesSU**	Class I devices that qualify as re-usable surgical instruments	N/A	MED 200068; NB1014

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/2/29	MIT/2024/P040	Initial issue