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	**Symbios Orthopédie S.A.**
Manufacturer address and contact details	**Avenue des Sciences 1,** **1400 Yverdon-les-Bains, SWITZERLAND** device@symbios.ch
Single Registration Number (SRN) (if available)	**CH-MF-000020168**

Authorised Representative name (if applicable)	**Symbios France SAS**
Authorised Representative address and contact details	**14 Rue d'Arsonval** **69680 Chassieu, FRANCE** info@symbios.ch
Single Registration Number (SRN) (if available)	**FR-AR-000017731**

Notified body name (if applicable)	**Elektrotechnický Zkušební Ústav (EZÚ)** ☐ See attached schedule
Notified body number (if applicable)	**1014** ☐ See attached schedule
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

[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.

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

  ☐ 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.

[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

☒ Expired/expires *after* 20 March 2023:

Annex I:

☒ 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.

Annex II:

☒ 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:

Full Company Name	**Symbios Orthopédie S.A.**
Location & Date	**Yverdon-les-Bains, 18-Aug-2023**
Signature, Print Name, Title	**Nicolas Guignet, VP Regulatory Affairs & Quality**
Contact Details (at least email)	device@symbios.ch

The above Manufacturer's Declaration is valid for the following devices (refer to Annex I and Annex II):

ANNEX I: Schedule of Devices for which formal application(s) has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024

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)
ORIGIN® Implants: **5000 1100, 5000 1300** **5000 2100, 5000 2300** **5000 2700, 5000 2800** **5000 3700, 5000 3701** **5000 3702, 5000 3703** **5000 3100, 5000 3102** **5000 3300, 5000 3302** **5000 4101, 5000 4102** **5000 4103, 5000 4104** **5000 4105**	**MED 180047** **MED 180048**	**14-Aug-2023**	**EZÚ (1014)**	**mdc (0483)**	**26-Sep-2024**	**Not Applicable**
ORIGIN® Instrumentation: **9005 0000, 9005 0011** **9005 0012, 9005 0013** **9005 0014, 9005 0015** **9005 0016, 9005 0021** **9005 0022, 9005 0023** **9005 0024, 9005 0025** **9005 0026, 9005 0027** **9005 0028, 9005 0029** **9005 0030, 9000 7801** **9000 7802, 9000 7803** **9000 7804, 9000 7805**	**MED 180074**	**17-Dec-2023**	**EZÚ (1014)**	**mdc (0483)**	**26-Sep-2024**	**Not Applicable**

[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)

INDIVIDUAL HIP® TiHA: 3000 0201	**MED 200052 MED 200053**	**26-May-2024**	**EZÚ (1014)**	**mdc (0483)**	**26-Sep-2024**	**3000 0202 3000 0203 3000 0204 3000 0205**
INDIVIDUAL HIP® Cemented: 3000 0301	**MED 200052 MED 200053**	**26-May-2024**	**EZÚ (1014)**	**mdc (0483)**	**26-Sep-2024**	**3000 0302 3000 0303**
INDIVIDUAL HIP® Instruments: 3000 0501, 3000 0511 3000 0701, 3000 0711	**MED 200054**	**26-May-2024**	**EZÚ (1014)**	**mdc (0483)**	**26-Sep-2024**	**Not Applicable**

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ANNEX II: Schedule of Devices for which the transition period will end on 26 May 2024

Identification of the device(s)[4] (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)
ORIGIN® Instrumentation: 9005 0020	**MED 180074**	**17-Dec-2023**	**EZÚ (1014)**	**Not Applicable**	**26-May-2024**	**Not Applicable**

[4] 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)