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)	**BSI** □ See attached schedule
Notified body number (if applicable)	**2797** □ 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:

- ☒ 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:

Full Company Name	**Symbios Orthopédie S.A.**
Location & Date	**Yverdon-les-Bains, 13-May-2024**
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:

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)
SERENITY® Cups: **1030 4200, 1030 4400** **1030 4600, 1030 4800** **1030 5000, 1030 5200** **1030 5400, 1030 5600** **1030 5800, 1030 6000** **1030 6200, 1030 6400**	**CE 650742** **CE 656220**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2027**	**Not Applicable**
SERENITY® Inserts: **1530 4210, 1530 4410** **1530 4610, 1530 4820** **1530 5020, 1530 5220** **1530 5420, 1530 5620** **1530 5820, 1530 6020** **1530 6220, 1530 6420**	**CE 650742** **CE 656220**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2027**	**Not Applicable**
APRIL® Ceramic: **1025 4000, 1025 4200** **1025 4400, 1025 4600** **1025 4800, 1025 5000** **1025 5200, 1025 5400** **1025 5600, 1025 5800** **1025 6000, 1025 6200** **1025 6400**	**CE 650742** **CE 682426**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2027**	**Not Applicable**
APRIL® Poly: **1027 4000, 1027 4200** **1027 4400, 1027 4600** **1027 4800, 1027 5000** **1027 5200, 1027 5201** **1027 5400, 1027 5600**	**CE 650742** **CE 682426**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2027**	**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)

1027 5800, 1027 6000 1027 6200, 1027 6400						
INLOCK X® Inserts: 1513 4010, 1513 4011 1513 4210, 1513 4211 1513 4410, 1513 4411 1513 4620, 1513 4621 1513 4820, 1513 4821 1513 5020, 1513 5021 1513 5030, 1513 5031 1513 5220, 1513 5221 1513 5230, 1513 5231 1513 5240, 1513 5241 1513 5420, 1513 5421 1513 5430, 1513 5431 1513 5440, 1513 5441 1513 5620, 1513 5621 1513 5630, 1513 5631 1513 5640, 1513 5641 1513 5820, 1513 5821 1513 5830, 1513 5831 1513 5840, 1513 5841 1513 6020, 1513 6021 1513 6030, 1513 6031 1513 6040, 1513 6041 1513 6220, 1513 6221 1513 6230, 1513 6231 1513 6240, 1513 6241 1513 6420, 1513 6421 1513 6430, 1513 6431 1513 6440, 1513 6441	CE 650742 CE 682425	26-May-2024 09-Feb-2024	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
BIOLOX® Delta Heads: 2014 2801, 2014 2802 2014 2803, 2014 3201 2014 3202, 2014 3203 2014 3204, 2014 3601 2014 3602, 2014 3603 2014 3604	CE 650742 CE 656216	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
BIOLOX® Delta Inserts: 1510 2835, 1510 3239	CE 650742 CE 656216	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable

1510 3644, 1510 3648						
Cobalt-Chrome Heads: 2010 2201, 2010 2202 2010 2204, 2010 2801 2010 2802, 2010 2803 2010 2804, 2010 3201 2010 3202, 2010 3203 2010 3204, 2010 3601 2010 3602, 2010 3603 2010 3604	CE 650742 CE 682482	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
Stainless Steel Heads: 2011 2801, 2011 2802 2011 2803, 2011 2804 2011 3201, 2011 3202 2011 3203, 2011 3204	CE 650742 CE 682482	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
SPS® HA: 3022 0200, 3022 0201 3022 0300, 3022 0301 3022 0400, 3022 0401 3022 0500, 3022 0501 3022 0600, 3022 0601 3022 0700, 3022 0701 3022 0800, 3022 0801	CE 650742 CE 656219	26-May-2024 26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
SPS® Evolution: 3023 0200, 3023 0201 3023 0300, 3023 0301 3023 0400, 3023 0401 3023 0500, 3023 0501 3023 0600, 3023 0601 3023 0700, 3023 0701 3023 0800, 3023 0801	CE 650742 CE 656219	26-May-2024 26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2027	Not Applicable
Spongious Bone Screw: 8001 6515, 8001 6520 8001 6525, 8001 6530 8001 6535, 8001 6540 8001 6545, 8001 6550 8001 6555, 8001 6560	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable
Hip plan software: 9000 0150	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable

HARMONY® Rasps: **7091 3010, 7091 3011** **7091 3012, 7091 3013** **7091 3014, 7091 3015** **7091 3016, 7091 3018** **7091 3020, 7091 3108** **7091 3109, 7091 4208** **7091 4209, 7091 4210** **7091 4211, 7091 4212** **7091 4213, 7091 4214** **7091 4215, 7091 4216** **7091 4218, 7091 4220**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**
SPS® Rasps: **7072 4020, 7072 4021** **7072 4030, 7072 4031** **7072 4040, 7072 4041** **7072 4050, 7072 4051** **7072 4060, 7072 4061** **7072 4070, 7072 4071** **7072 4080, 7072 4081**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**
Reamer: 7002 3002	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**
Trial cups: **7103 3040, 7103 3042** **7103 3044, 7103 3046** **7103 3048, 7103 3050** **7103 3052, 7103 3054** **7103 3056, 7103 3058** **7103 3060, 7103 3062** **7103 3064**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**
Trial Heads: **7003 4122, 7003 4222** **7003 4422, 7003 4128** **7003 4228, 7003 4328** **7003 4428, 7003 4132** **7003 4232, 7003 4332** **7003 4432, 7003 4136** **7003 4236, 7003 4336** **7003 4436**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**
SERENITY® Trial inserts:	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**31-Dec-2028**	**Not Applicable**

7230 2242, 7230 2244 7230 2246, 7230 2848 7230 2850, 7230 2852 7230 2854, 7230 2856 7230 2858, 7230 2860 7230 2862, 7230 2864						
SPS® HA Trial Necks: 7073 9002, 7073 9003	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable
SPS® Evolution Trial Necks: 7073 9007, 7073 9008 7073 9009, 7073 9010	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable
Threaded Pin: 9000 0031	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable
Stop Drill Bits: 9000 4003, 9000 4004 9000 4005	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	31-Dec-2028	Not Applicable