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:

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:

Annex III:

☒ 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.

Annex IV:

☒ 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, Annex II, Annex III and Annex IV):

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)
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)**	**26-Sep-2024**	**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)**	**26-Sep-2024**	**Not Applicable**
APRIL® Ceramic: **1025 4000, 1025 4200** **1025 4400, 1025 4600** **1025 4800, 1025 5000** **1025 5200, 1025 5400** **1025 5600, 1025 8000** **1025 6000, 1025 6200** **1025 6400**	**CE 650742** **CE 682426**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**mdc (0483)**	**26-Sep-2024**	**Not Applicable**
APRIL® Poly: **1027 4000, 1027 4200**	**CE 650742** **CE 682426**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**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)

1027 4400, 1027 4600 1027 4800, 1027 5000 1027 5200, 1027 5201 1027 5400, 1027 5600 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)	26-Sep-2024	Not Applicable
BIOLOX® Delta Heads: 2014 2801, 2014 2802 2014 2803, 2014 3201 2014 3202, 2014 3203 2014 3204, 2014 3601	CE 650742 CE 656216	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable

2014 3602, 2014 3603 2014 3604						
BIOLOX® Delta Inserts: 1510 2835, 1510 3239 1510 3644, 1510 3648	CE 650742 CE 656216	26-May-2024 22-May-2023	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable
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)	26-Sep-2024	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)	26-Sep-2024	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)	26-Sep-2024	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)	26-Sep-2024	Not Applicable
Spongious Bone Screw: 8001 6515, 8001 6520 8001 6525, 8001 6530 8001 6535, 8001 6540	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024 (In Progress)	Not Applicable

8001 6545, 8001 6550 8001 6555, 8001 6560						
Hip plan software: 9000 0150	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024 (In Progress)	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)	26-Sep-2024	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)	26-Sep-2024	Not Applicable
Reamer: 7002 3002	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024 (In progress)	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)	26-Sep-2024	Not Applicable
Trial Heads: 7003 4122, 7003 4222 7003 4422, 7003 4128 7003 4228, 7003 4328 7003 4428, 7003 4132	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable

7003 4232, 7003 4332 7003 4432, 7003 4136 7003 4236, 7003 4336 7003 4436						
SERENITY® Trial inserts: 7230 2242, 7230 2244 7230 2246, 7230 2848 7230 2850, 7230 2852 7230 2854, 7230 2856 7230 2858, 7230 2860 7230 2862, 7230 2864	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable
SPS® HA Trial Necks: 7073 9002, 7073 9003	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable
SPS® Evolution Trial Necks: 7073 9007, 7073 9008 7073 9009, 7073 9010	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable
Threaded Pin: 9000 0031	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable
Stop Drill Bits: 9000 4003, 9000 4004 9000 4005	CE 650742	26-May-2024	BSI (2797)	mdc (0483)	26-Sep-2024	Not Applicable

symbios

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)
SERENITY® Impaction Plate: **SE102 400, SE102 401** **SE102 402, SE102 403** **SE102 404, SE102 405** **SE102 406, SE102 407** **SE102 408, SE102 409** **SE102 410, SE102 411**	**CE 650742** **CE 656220**	**26-May-2024** **09-Feb-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
BIOLOX® Delta Heads: **2014 4001, 2014 4002** **2014 4003, 2014 4004**	**CE 650742** **CE 656216**	**26-May-2024** **22-May-2023**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
BIOLOX® Delta Inserts: **1510 4048**	**CE 650742** **CE 656216**	**26-May-2024** **22-May-2023**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
BIOLOX® Forte Heads: **2009 2801, 2009 2802** **2009 2803, 2009 3201** **2009 3202, 2009 3203**	**CE 650742** **CE 656216**	**26-May-2024** **22-May-2023**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
ARCAD® HA: **3028 0100, 3028 0200** **3028 0300, 3028 0400** **3028 0500, 3028 0600** **3028 0700, 3028 0800** **3028 0900**	**CE 650742** **CE 656218**	**26-May-2024** **11-Apr-2023**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
ARCAD® SO: **3030 0100, 3030 0200** **3030 0300, 3030 0400**	**CE 650742** **CE 656218**	**26-May-2024** **11-Apr-2023**	**BSI (2797)**	**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)

3030 0500, 3030 0600 3030 0700, 3030 0800 3030 0900						
ARCAD® LONG: 3029 0200, 3029 0300 3029 0400, 3029 0500 3029 0600, 3029 0700 3029 0800	CE 650742 CE 656218	26-May-2024 11-Apr-2023	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® XL: 3029 0302, 3029 0402 3029 0502, 3029 0602	CE 650742 CE 656218	26-May-2024 11-Apr-2023	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HILOCK®: 1010 4600, 1010 4800 1010 5000, 1010 5200 1010 5400, 1010 5600 1010 5800, 1010 6000 1010 6200, 1010 6400	CE 650742 CE 682478	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HILOCK® LINE: 1017 4000, 1017 4200 1017 4400, 1017 4600 1017 4800, 1017 5000 1017 5200, 1017 5400 1017 5600, 1017 5800 1017 6000, 1017 6200 1017 6400, 1017 6600, 1017 6800, 1017 7000	CE 650742 CE 682478	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HILOCK® REV: 1007 4000, 1007 4200 1007 4400, 1007 4600 1007 4800, 1007 5000 1007 5200, 1007 5400 1007 5600, 1007 5800 1007 6000, 1007 6200 1007 6400, 1007 6600, 1007 6800, 1007 7000	CE 650742 CE 682478	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Modular Necks: 3314 0002, 3314 0003 3314 1082, 3314 1083 3314 2152, 3314 2153	CE 650742 CE 682496	26-May-2024 06-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

3314 4002, 3314 4003 3314 4012, 3314 4013						
HARMONY®: 3031 0900, 3031 1000 3031 1100, 3031 1200 3031 1300, 3031 1400 3031 1500, 3031 1600 3031 1800, 3031 2000	CE 650742 CE 682479	26-May-2024 22-May-2023	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HARMONY® Cemented: 3034 0800, 3034 0900 3034 1000, 3034 1100 3034 1200, 3034 1300 3034 1400, 3034 1500 3034 1600	CE 650742 CE 682480	26-May-2024 22-May-2023	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Femur Cemented: 5002 1021, 5002 1022 5002 1023, 5002 1024 5002 1025, 5002 1026 5002 1031, 5002 1032 5002 1033, 5002 1034 5002 1035, 5002 1036	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Femur Cementless: 5004 1021, 5004 1022 5004 1023, 5004 1024 5004 1025, 5004 1026 5004 1031, 5004 1032 5004 1033, 5004 1034 5004 1035, 5004 1036	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST REV Femur Cemented: 5003 1001, 5003 1002 5003 1003, 5003 1004 5003 1005, 5003 1011 5003 1012, 5003 1013 5003 1014, 5003 1015	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Mobile Tibia Monobloc Cemented: 5005 2100, 5005 2200	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

5005 2300, 5005 2400 5005 2500, 5005 2600						
Tibial Guide Pin Monobloc: 5002 6300	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Mobile Tibia Modular Cemented: 5002 2100, 5002 2200 5002 2300, 5002 2400 5002 2500, 5002 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Mobile Tibia Monobloc Cementless: 5006 2100, 5006 2200 5006 2300, 5006 2400 5006 2500, 5006 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Knee Modular Stem: 5010 5100, 5010 5200 5010 5300, 5010 5400	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Tibial Guide Pin Modular: 5002 6100, 5002 6200	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Sensitive Tibial Guide Pin Monobloc: 5012 6300	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Sensitive Tibial Guide Pin Modular: 5010 6100, 5010 6200	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Patella: 5002 4100, 5002 4200 5002 4300, 5002 4400	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Mobile Insert: 5002 3031, 5002 3032 5002 3033, 5002 3034 5002 3035, 5002 3041 5002 3042, 5002 3043 5002 3044, 5002 3045 5002 3051, 5002 3052 5002 3053, 5002 3054 5002 3055	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST REV Mobile Insert: 5003 3001, 5003 3002	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

5003 3003, 5003 3004 5003 3005, 5003 3011 5003 3012, 5003 3013 5003 3014, 5003 3015 5003 3021, 5003 3022 5003 3023, 5003 3024 5003 3025						
FIRST Fixed Insert: 5007 3001, 5007 3002 5007 3003, 5007 3004 5007 3005, 5007 3011 5007 3012, 5007 3013 5007 3014, 5007 3015 5007 3021, 5007 3022 5007 3023, 5007 3024 5007 3025	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Fixed Tibia Monobloc Cemented: 5008 2100, 5008 2200 5008 2300, 5008 2400 5008 2500, 5008 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Fixed Tibia Monobloc Cementless: 5009 2100, 5009 2200 5009 2300, 5009 2400 5009 2500, 5009 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Sensitive Femur Cemented: 5010 1021, 5010 1022 5010 1023, 5010 1024 5010 1025, 5010 1026 5010 1031, 5010 1032 5010 1033, 5010 1034 5010 1035, 5010 1036	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Sensitive Mobile Tibia Modular Cemented: 5010 2100, 5010 2200 5010 2300, 5010 2400 5010 2500, 5010 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

Sensitive Knee Modular Stem: 5010 5100, 5010 5200 5010 5300, 5010 5400	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Sensitive Mobile Tibia Monobloc Cemented: 5012 2100, 5012 2200 5012 2300, 5012 2400 5012 2500, 5012 2600	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST REV Sensitive Femur Cemented: 5015 1021, 5015 1022 5015 1023, 5015 1024 5015 1025, 5015 1031 5015 1032, 5015 1033 5015 1034, 5015 1035	CE 650742 CE 656221	26-May-2024 04-Feb-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Drill Bits: 7018 1009, 7019 4002, 7019 4003	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HARMONY® Rasps: 7091 4008, 7091 4009 7091 4010, 7091 4011 7091 4012, 7091 4013 7091 4014, 7091 4015 7091 4016, 7091 4018 7091 4020	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ATLANTIS Rasps: 7019 2011, 7019 2010 7019 2021, 7019 2020 7019 2031, 7019 2030 7019 2041, 7019 2040 7019 2051, 7019 2050	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
SPS® Compactors: 7072 3020, 7072 3021 7072 3030, 7072 3031 7072 3040, 7072 3041 7072 3050, 7072 3051 7072 3060, 7072 3061	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

7072 3070, 7072 3071 7072 3080, 7072 3081						
ARCAD Long Trial Stem Extension: 7046 2000, 7046 2030 7046 2040, 7046 2050 7046 2060	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® Rasps: 7042 3010, 7042 3020 7042 3030, 7042 3040 7042 3050, 7042 3060 7042 3070, 7042 3080 7042 3090	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Reamer: 7002 3001	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial cups: 7103 3066	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial Heads: 7003 4140, 7003 4240, 7003 4340, 7003 4440	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial Inserts: 7107 2400, 7107 2401 7107 2420, 7107 2421 7107 2440, 7107 2441 7107 4460, 7107 4461 7107 4480, 7107 4481 7107 4500, 7107 4501 7107 4520, 7107 4521 7107 4540, 7107 4541 7107 4560, 7107 4561 7107 4580, 7107 4581 7107 4600, 7107 4601 7107 4620, 7107 4621 7107 4640, 7107 4641 7107 5500, 7107 5501 7107 5520, 7107 5521 7107 5540, 7107 5541 7107 5560, 7107 5561 7107 5580, 7107 5581 7107 5600, 7107 5601 7107 5620, 7107 5621	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

7107 5640, 7107 5641 7107 6520, 7107 6521 7107 6540, 7107 6541 7107 6560, 7107 6561 7107 6580, 7107 6581 7107 6600, 7107 6601 7107 6620, 7107 6621 7107 6640, 7107 6641						
APRIL® Trial Inserts: 7126 28350, 7126 28390 7126 28440, 7126 28480 7126 32390, 7126 32440 7126 36440, 7126 36480	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
MODULAR Trial Necks: 7073 4002, 7073 4003 7073 4082, 7073 4083 7073 4152, 7073 4153 7073 4172, 7073 4173 7073 4182, 7073 4183	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® Trial necks: 7043 3010, 7043 3020 7043 3030, 7043 3040 7043 3050, 7043 3060 7043 3070, 7043 3080 7043 3090	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
HARMONY® Trial Necks: 7073 9011, 7073 9012	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® Long Trial Stem: 7045 3020, 7045 3030 7042 3040, 7042 3050 7042 3060, 7042 3070 7042 3080	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® Long Trial Stem Extension: 7046 2000	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
ARCAD® XL Trial Stem Extension: 7046 2030, 7046 2040, 7046 2050, 7046 2060	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
IM Drill Bit: 9000 4001	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

Threaded Pin: 9000 0021	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST KNEE-PLAN® Guide: 9000 0000	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
KNEE-PLAN® Set: 9000 6000	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Single-Use Femur Sets: 9000 8026, 9000 8027 9000 8029, 9000 8030 9000 8031	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Single-Use Tools Set: 9000 8032	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Mobile Single-Use Tibia Sets: 9000 8033, 9000 8034 9000 8035, 9000 8036 9000 8037, 9000 8038	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Fixed Single-Use Tibia Sets: 9000 8039, 9000 8040 9000 8041, 9000 8042 9000 8043, 9000 8044	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Trial Femur: 9100 1021, 9100 1022 9100 1023, 9100 1024 9100 1025, 9100 1026 9100 1031, 9100 1032 9100 1033, 9100 1034 9100 1035, 9100 1036	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST REV Trial Femur: 9103 1001, 9103 1002 9103 1003, 9103 1004 9103 1005, 9103 1011 9103 1012, 9103 1013 9103 1014, 9103 1015	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
FIRST Mobile trial inserts: 9300 1003, 9300 1103 9300 1203, 9300 1503 9300 1703, 9300 1004	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**

9300 1104, 9300 1204 9300 1504, 9300 1704 9300 1005, 9300 1105 9300 1205, 9300 1505 9300 1705						
FIRST REV trial inserts: 9303 1000, 9303 1100 9303 1200, 9303 1500 9303 1700, 9303 1001 9303 1101, 9303 1201 9303 1501, 9303 1701 9303 1002, 9303 1102 9303 1202, 9303 1502 9303 1702	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Fixed trial inserts: 9307 1000, 9307 1100 9307 1200, 9307 1500 9307 1700, 9307 1001 9307 1101, 9307 1201 9307 1501, 9307 1701 9307 1002, 9307 1102 9307 1202, 9307 1502 9307 1702	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
FIRST Patella trial components: 9400 1001, 9400 1002 9400 1003, 9400 1004	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial Tibial Stems: 9000 5001, 9000 5002 9000 5003, 9000 5005	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial Stems: 9003 5001, 9003 5002 9003 5003, 9003 5004	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable
Trial tibia: 9200 1001, 9200 1002 9200 1003, 9200 1004 9200 1005, 9200 1006	CE 650742	26-May-2024	BSI (2797)	Not Applicable	26-May-2024	Not Applicable

ANNEX III: Schedule of upclassified devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body and 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)[5] (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)
Hip reusable surgical instruments: **7004 1000, 7004 2236** **7004 3656, 7004 4001** **7004 4008, 7004 4009** **7004 4013, 7004 4015** **7004 4017, 7004 4018** **7004 402X, 7004 4025** **7006 1008, 7006 1009** **7006 1012, 7006 1013** **7006 1014, 7006 1015** **7006 1016, 7006 1019** **7006 1020, 7006 1021** **7006 1022, 7006 1023** **7006 1024, 7012 2002** **7012 2003, 7012 2004** **7012 2005, 7012 2006** **7014 4000, 7014 4001** **7016 2002, 7104 20XX** **7104 21XX, 7104 3060** **7104 3061, 7104 3062** **7104 4002, 7104 4010** **7104 4011, 7104 4012** **7104 4020, 7104 4030** **7104 7005, 7105 1006**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**26-Sep-2024** (In Progress)	**Not Applicable**

[5] 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)

7105 2016, 7105 2020 7105 3001, 7105 5000 7230 1000, 7230 1001 7230 1002, 7230 3000 7230 3001, 7800 1000 7800 3920, 7800 3921 7800 3946, 7800 5000, PR100 011						
Knee reusable surgical instruments: 9000 0003, 9000 0008 9400 0001, 9400 0002 9400 200X, PD000069	**CE 650742**	**26-May-2024**	**BSI (2797)**	**mdc (0483)**	**26-Sep-2024** (In Progress)	**Not Applicable**

ANNEX IV: Schedule of upclassified devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body and for which the transition period will end on 26 May 2024

Identification of the device(s)[6] (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)
Hip reusable surgical instruments: **7007 0204, 7007 0205** **7034 2012, 7073 0001** **7074 1002, 7074 2001** **7104 3010, 7104 3015** **7104 3016, 7104 4001** **7104 5012, 7105 2011** **7800 3925, 7800 3927** **7800 4001, PR102 025**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**
Knee reusable surgical instruments: **9000 0005, 9000 0007** **9000 0011, 9000 0013** **9000 0018, 9000 0026** **9000 0027, 9000 0029** **9000 0030, 9000 0032** **9000 0034, 9000 0045** **9000 0046, 9000 0050** **9100 0002, 9100 0003** **9100 0005, 9100 0006** **9100 0008, 9100 0013** **9100 0014, 9100 0017** **9100 002X, 9100 120x** **9100 1300, 9103 0005** **9200 0001, 9200 0002**	**CE 650742**	**26-May-2024**	**BSI (2797)**	**Not Applicable**	**26-May-2024**	**Not Applicable**

[6] 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)

9200 0003, 9200 0004 9200 0005, 9200 0006 9200 0007, 9200 0008 9200 0009, 9200 0010 9200 0011, 9200 110x 9203 0006, 9203 0007 9203 0008, 9203 0011 9203 0021, 9303 0001 9100 0016, PD000067 PD000068						