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	Acumed LLC
Manufacturer address and contact details	5885 NE Cornelius Pass Rd Hillsboro, OR 97124 USA PRRC: Kathryn A. Jayne 972-677-4766, kathryn.jayne@acumed.net
Single Registration Number (SRN) (if available)	US-MF-000023121

Authorised Representative name (if applicable)	Emergo Europe
Authorised Representative address and contact details	Westervoortsedijk 60 6827 AP Arnhem The Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000000116

[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.

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)	CE 654449 See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-08-10 □ See attached schedule
End date of extended validity/transition period	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 reusable surgical instruments) □ 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,

[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

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.

  ☒ 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:

Acumed LLC
5885 NE Cornelius Pass Road
Hillsboro, OR 97124

10 January 2025

Kathryn Jayne (Jan 10, 2025 14:14 CST)

Kathryn A. Jayne
Vice President, Quality Assurance & Regulatory Affairs
kathryn.jayne@acumed.net

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)
Congruent Bone Plating System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
ARH System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2027 (Class IIB/III) 31 Dec 2028 (Class IIa)	n/a
Acutrak screws	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Cannulated Screws	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
AcuSinch	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Bone graft System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
External Fixation System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Polarus Humeral Rod	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Small Bone / FFN2	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Tension Band Pin	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Wrist Spanning	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Ankle Plating System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Hand Plating	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Pelvic Plating System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Polarus 3	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Small Fragment base Set	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Wrist Fusion	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	n/a
Rib Plating System	CE 654449	2023-08-10	BSI 2797	BSI 2797	31 Dec 2028	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)

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)
OSTEOSYNTHESIS INSTRUMENTS, REUSABLE - OTHERS [0806378BUDI35Q5]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
ORTHOPAEDIC PROSTHESES REAMERS AND BURS [0806378BUDI37Q9]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
ORTHOPAEDIC PROSTHESES INSTRUMENTS, REUSABLE - OTHERS [0806378BUDI40PW]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
RASPATORIES, ORTHOPAEDIC SURGERY [0806378BUDI42Q2]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
GRASPING FORCEPS, BONE [0806378BUDI43Q4]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
FORCEPS, BONE REDUCTION [0806378BUDI44Q6]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
ORTHOPAEDIC ELEVATORS, PERIOSTEAL [0806378BUDI45Q8]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a

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)
ORTHOPAEDIC SURGERY DILATORS AND RETRACTORS [0806378BUDI46QA]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
INSTRUMENTS FOR INSERTION AND EXTRACTION OF OSTEOSYNTHESIS DEVICES [0806378BUDI52Q5]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a
OSTEOSYNTHESIS INSTRUMENTS, REUSABLE - OTHERS [0806378BUDI35Q5]	n/a – Device did not require a NB certificate under MDD	n/a	n/a	BSI 2797	31 Dec 2028	n/a

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Acumed_MDR_Manufacturer Declaration_Updated

Final Audit Report 2025-01-10

Created:	2025-01-10
By:	Tiffanylee Horn (tiffanylee.horn@acumed.net)
Status:	Signed
Transaction ID:	CBJCHBCAABAAEO9wvWMDmT0EIFXlLzsnMOEFyR6IfiDU

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2025-01-10 - 7:24:56 PM GMT- IP address: 47.184.147.227

Document emailed to Kathryn Jayne (kathryn.jayne@acumed.net) for signature
2025-01-10 - 7:26:03 PM GMT

Email viewed by Kathryn Jayne (kathryn.jayne@acumed.net)
2025-01-10 - 8:13:18 PM GMT- IP address: 104.47.55.126

Document e-signed by Kathryn Jayne (kathryn.jayne@acumed.net)
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Agreement completed.
2025-01-10 - 8:14:25 PM GMT