

ADSM
7b rue Lavoisier
69680 CHASSIEU - FRANCE
Tel : +33 (0)4 28 71 03 10
Fax : +33 (0)4 28 71 03 20
office@synchronmedical.com

REF : DT007-016-EN Rev14

Single registration number : FR-MF-000001222

Chassieu, July 4, 2025

EU DECLARATION OF CONFORMITY

ADSM, represented by Luigi BIVI, President, hereby certifies, under his sole responsibility, that the following medical devices comply with all the provisions of Medical Device Regulation dated April, 5th 2017 and with provisions from the Public Health Code, section 5, book number II, 1st Title (article R665-1 et al., if applicable).

This declaration is based on:

- The technical file DT007 demonstrating compliance with General Safety and Performance Requirements of MDR 2017/745
- The full quality assurance system certification (certificate N° SX 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY.
- MDR 2017/745 EC certificate (certificate N°HZ 1551305-1) delivered by TÜV RHEINLAND LGA PRODUCTS GmbH (Notified body number 0197), Tillystraße 2, 90431 Nürnberg, GERMANY, as per conformity assessment procedure of Annex IX, Chapter I, Sections 2 and 3 and Chapter III.

This for the period of validity of the certificate until: 2026/10/12.

NB: this declaration is only valid in combination with a specific batch release document.

Luigi BIVI
President

Lise ROLLY TAYMANS
PRRC

DocuSigned by:

Indications

DocuSigned by:



BA4C49EBBAFC45E...



731F3E37D03648E...

.These medical devices are only indicated for patient with a body mass superior or equal to 10kg.
Kirschner wires (transient use)
These devices are indicated for:
- temporary stabilization of bone fragments during surgery
- as a guidance system for product-specific medical devices
Kirschner wires (long-term use)
These devices are indicated for long-term fixation of bone segments in order to obtain bone fusion, both in a percutaneous or open surgical approach.
Guide wires (transient use)
These devices are indicated as a guidance system for product-specific medical devices

Reference	Designation	Class	Classification rule	UDI-DI code	EMDN code (CND)	BUDI-DI code	Brand Name
00-2490-450-32-R	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091006755	L091001	037010910DT007KWNONSTEUZ	SterileBitz
00-2490-450-32-SB	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091006762	L091001	037010910DT007KWSTEPH	SterileBitz
02.01362.116-R	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007097	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
02.01362.116-SB	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007103	P09120301	037010910DT007KWSTEPH	SterileBitz
110.25.000-R	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007264	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
110.25.000-SB	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007259	P09120301	037010910DT007KWSTEPH	SterileBitz
2810-01-175-R	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091006779	L091001	037010910DT007KWNONSTEUZ	SterileBitz
2810-01-175-SB	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091006786	L091001	037010910DT007KWSTEPH	SterileBitz
290.06.070-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007073	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.06.070-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007080	P09120301	037010910DT007KWSTEPH	SterileBitz
290.08.070-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007059	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.08.070-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007066	P09120301	037010910DT007KWSTEPH	SterileBitz
290.10.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007035	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.10.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007042	P09120301	037010910DT007KWSTEPH	SterileBitz
290.12.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007011	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.12.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007028	P09120301	037010910DT007KWSTEPH	SterileBitz
290.14.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006991	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.14.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007004	P09120301	037010910DT007KWSTEPH	SterileBitz
290.14.280-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006977	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.14.280-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006984	P09120301	037010910DT007KWSTEPH	SterileBitz
290.16.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006953	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.16.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006960	P09120301	037010910DT007KWSTEPH	SterileBitz
290.16.280-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006939	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.16.280-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006946	P09120301	037010910DT007KWSTEPH	SterileBitz
290.18.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006915	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.18.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006922	P09120301	037010910DT007KWSTEPH	SterileBitz
290.18.280-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006892	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.18.280-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006908	P09120301	037010910DT007KWSTEPH	SterileBitz
290.20.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006878	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.20.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006885	P09120301	037010910DT007KWSTEPH	SterileBitz
290.20.280-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006854	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.20.280-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006861	P09120301	037010910DT007KWSTEPH	SterileBitz
290.25.150-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006830	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.25.150-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006847	P09120301	037010910DT007KWSTEPH	SterileBitz
290.25.280-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006816	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.25.280-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006823	P09120301	037010910DT007KWSTEPH	SterileBitz
290.25.310-R	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006793	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
290.25.310-SB	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091006809	P09120301	037010910DT007KWSTEPH	SterileBitz
299.20.150-R	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007110	P09120301	037010910DT007KWNONSTEUZ	SterileBitz
299.20.150-SB	EN-KIRSCHNER WIRE WITH THREADED TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007127	P09120301	037010910DT007KWSTEPH	SterileBitz
GW32444T	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003471	L091001	037010910DT007GWNONSTEMS	MISteri
GW32444TS-0101	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003464	L091001	037010910DT007GWNSTEMS	MISteri
GW32450T	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003495	L091001	037010910DT007GWNONSTEMS	MISteri
GW32450TS-0101	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003488	L091001	037010910DT007GWNSTEMS	MISteri
GW32508T	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003518	L091001	037010910DT007GWNONSTEMS	MISteri
GW32508TS-0101	EN-PARTIAL THREADED GUIDE WIRE	Ila	Annex VIII, Chapter III rule 6	03701091003501	L091001	037010910DT007GWNSTEMS	MISteri
KW06070TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002702	P09120301	037010910DT007KWNONSTEUZ	MISteri
KW06070TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002696	P09120301	037010910DT007KWSTEPH	MISteri
KW08070TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002726	P09120301	037010910DT007KWNONSTEUZ	MISteri
KW08070TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002719	P09120301	037010910DT007KWSTEPH	MISteri
KW08100TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002740	P09120301	037010910DT007KWCRCRNOSTEPW	MISteri
KW08100TRS-0102	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002733	P09120301	037010910DT007KWCRCRSTEUZ	MISteri
KW08100TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007219	P09120301	037010910DT007KWCRCRSTEUZ	MISteri
KW08150TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002764	P09120301	037010910DT007KWNONSTEUZ	MISteri
KW08150TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002757	P09120301	037010910DT007KWSTEPH	MISteri
KW10070TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002788	P09120301	037010910DT007KWNONSTEUZ	MISteri
KW10070TRS-0102	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002771	P09120301	037010910DT007KWSTEPH	MISteri
KW10070TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007226	P09120301	037010910DT007KWSTEPH	MISteri
KW10100TR	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002801	P09120301	037010910DT007KWNONSTEUZ	MISteri
KW10100TRS-0102	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091002795	P09120301	037010910DT007KWSTEPH	MISteri
KW10100TRS-0301	EN-KIRSCHNER WIRE WITH TROCER TIP	Ilb	Annex VIII, Chapter III rule 8	03701091007233	P09120301	037010910DT007KWSTEPH	MISteri

2/2