SynchroMedical
The interphalangeal reference

REF : DT007-016-EN Rev13

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Single registration number : FR-MF-000001222

Chassieu, October 22nd , 2024

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).

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Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
KW12150TTRS-0301	STERILE KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091002535	P091203	037010910DT007KWSTEPH	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
KW16150TTRS-0301				03701091002559			
KW18150TTRS-0301				03701091002573			
KW20150TTRS-0301				03701091002597			
KW25150TTRS-0301				03701091002610			
KW25200TTRS-0301				03701091002634			
KW30150TTRS-0301				03701091002658			
KW16190TTRS-0301				03701091002672			
KW06070TRS-0301	STERILE KIRSCHNER WIRE WITH TROCAR TIP			03701091002696			
KW08070TRS-0301				03701091002719			
KW08100TRS-0301				03701091007219		037010910DT007KWCRSTEUZ	
KW08100TRS-0102				03701091002733			
KW08150TRS-0301				03701091002757		037010910DT007KWSTEPH	
KW10070TRS-0301				03701091007226			
KW10070TRS-0102				03701091002771			
KW10100TRS-0301				03701091007233			
KW10100TRS-0102				03701091002795			
KW10150TRS-0301				03701091002818			
KW10280TRS-0301				03701091002832			
KW10310TRS-0301				03701091002856			
KW12150TRS-0301				03701091002870			
KW12150TRS-0102				03701091002887			
KW12280TRS-0301				03701091002900			
KW12310TRS-0301				03701091002924			
KW13100TRS-0301				03701091002948			
KW13100TRS-0102				03701091007318			
KW13050TRS-0301				03701091002962			
KW13050TRS-0102				03701091007240			
KW14150TRS-0301				03701091002986			
KW14280TRS-0301				03701091003006			
KW14310TRS-0301				03701091003020			
KW15100TRS-0301				03701091007325			
KW15100TRS-0102				03701091003044			

KW15150TRS-0301				03701091007332			
KW15150TRS-0102				03701091003068			
KW16150TRS-0301				03701091003082			
KW16280TRS-0301				03701091003105			
KW16310TRS-0301				03701091003129			
KW18150TRS-0301				03701091003143			
KW18280TRS-0301				03701091003167			
KW18310TRS-0301				03701091003181			
KW20150TRS-0301				03701091003204			
KW20280TRS-0301				03701091003228			
KW20310TRS-0301				03701091003242			
KW20400TRS-0301				03701091003266			
KW22450TRS-0301				03701091003280			
KW25150TRS-0301				03701091003303			
KW25280TRS-0301				03701091003327			
KW25310TRS-0301				03701091003341			
KW25400TRS-0301				03701091003365			
KW30150TRS-0301				03701091003389			
KW30280TRS-0301				03701091003402			
KW30310TRS-0301				03701091003426			
KW30400TRS-0301				03701091003440			
GW32444TS-0101	STERILE PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091003464	L091001	03701091DT007GWST EN5	
GW32450TS-0101				03701091003488			
GW32508TS-0101				03701091003501			

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Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
KW12150TTR	KIRSCHNER WIRE WITH THREADED TIP	IIb	Annex VIII, Chapter III Rule 8	03701091002542	P091203	03701091DT007KWNONSTEUZ	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
KW16150TTR				03701091002566			
KW18150TTR				03701091002580			
KW20150TTR				03701091002603			
KW25150TTR				03701091002627			
KW25200TTR				03701091002641			
KW30150TTR				03701091002665			
KW16190TTR				03701091002689			
KW06070TR	KIRSCHNER WIRE WITH TROCAR TIP			03701091002702			
KW08070TR				03701091002726			
KW08100TR				03701091002740		0370109 10DT007 KWCRNO STEPW	
KW08150TR				03701091002764		03701091DT007KWNONSTEUZ	
KW10070TR				03701091002788			
KW10100TR				03701091002801			
KW10150TR				03701091002825			
KW10280TR				03701091002849			
KW10310TR				03701091002863			
KW12150TR				03701091002894			
KW12280TR				03701091002917			
KW12310TR				03701091002931			
KW13100TR				03701091002955			
KW13050TR				03701091002979			

KW14150TR				03701091002993			
KW14280TR				03701091003013			
KW14310TR				03701091003037			
KW15100TR				03701091003051			
KW15150TR				03701091003075			
KW16150TR				03701091003099			
KW16280TR				03701091003112			
KW16310TR				03701091003136			
KW18150TR				03701091003150			
KW18280TR				03701091003174			
KW18310TR				03701091003198			
KW20150TR				03701091003211			
KW20280TR				03701091003235			
KW20310TR				03701091003259			
KW20400TR				03701091003273			
KW22450TR				03701091003297			
KW25150TR				03701091003310			
KW25280TR				03701091003334			
KW25310TR				03701091003358			
KW25400TR				03701091003372			
KW30150TR				03701091003396			
KW30280TR				03701091003419			
KW30310TR				03701091003433			
KW30400TR				03701091003457			
GW32444T	PARTIAL THREADED GUIDE WIRE	IIa	Annex VIII, Chapter III Rule 6	03701091003471	L091001	037010910DT007GWNONSTESM	
GW32450T				03701091003495			
GW32508T				03701091003518			

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

DocuSigned by:
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Lise ROLLY TAYMANS
PRRC

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Lise Taymans
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