SynchroMedical
The interphalangeal reference

REF : DT009-016 EN Rev11

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Single registration number : FR-MF-000001222

Chassieu, September 13th 2024

EC CONFORMITY DECLARATION

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).

STERILEBITZ							
Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
02.00024.001-SB	STERILE TWO-FLUTED DRILL BIT WITH QUICK COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091006748	L1104	037010910DT009DBSTEHB	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
02.00024.002-SB				03701091006724			
02.00024.003-SB				03701091006700			
02.00024.118-SB				03701091006687			
02.00024.125-SB				03701091006489			
02.00024.133-SB				03701091006465			
02.00024.143-SB				03701091006441			
02.00024.215-SB				03701091006663			
02.00024.301-SB				03701091006540			
02.00024.325-SB				03701091006526			
02.00024.330-SB				03701091006502			
02.00024.342-SB				03701091006649			
02.00024.344-SB				03701091006625			
02.00024.346-SB				03701091006601			
02.02024.360-SB				03701091006588			
103.25.180-SB				03701091006564			
103.25.180-SB				03701091007271			
02.00024.117-SB	STERILE FOUR-FLUTED CANNULATED DRILL BIT WITH QUICK COUPLING			03701091006427			
02.00024.233-SB				03701091006403			
20ZBCD140ST	STERILE THREE-FLUTED CANNULATED DRILL BIT WITH QUICK COUPLING			03701091006359			
24ZBCD140ST				03701091006366			
27ZBCD170ST				03701091006373			
35ZBCD170ST				03701091006380			

STERILEBITZ							
Reference	**Designation**	**Class**	**Classification rule**	**UDI-DI code**	**CND code**	**BUDI-DI code**	**Indication**
02.00024.001-R	TWO-FLUTED DRILL BIT WITH QUICK COUPLING	IIa	Annex VIII, Chapter III Rule 6	03701091006731	L1104	037010910DT009DBNONSTEF5	These medical devices are only indicated for patient with a body mass superior or equal to 10kg. These devices are indicated for bone preparation during orthopaedic surgery.
02.00024.002-R				03701091006717			
02.00024.003-R				03701091006694			
02.00024.118-R				03701091006410			
02.00024.125-R				03701091006670			
02.00024.133-R				03701091006472			
02.00024.143-R				03701091006458			
02.00024.215-R				03701091006434			
02.00024.301-R				03701091006656			
02.00024.325-R				03701091006397			
02.00024.330-R				03701091006533			
02.00024.342-R				03701091006519			
02.00024.344-R				03701091006496			
02.00024.346-R				03701091006632			
02.02024.360-R				03701091006618			
103.25.180-R				03701091006595			
103.32.145-R				03701091006571			
02.00024.117-R	FOUR-FLUTED CANNULATED DRILL BIT WITH QUICK COUPLING			03701091006410			
02.00024.233-R				03701091006397			

This declaration is based on:

- The technical file DT009 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.

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:
BA4C49EBBAFC45E...

Lise ROLLY TAYMANS
PRRC

DocuSigned by:
Lise Taymans
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