

**EU MDR DECLARATION OF
CONFORMITY**

Effective date: 02. Aug. 2021



ZIMMER BIOMET

SAP Title: MDR DoC NCB System Instruments
SAP Document: RA1-439623-EN-02

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**EU DECLARATION OF CONFORMITY
EN (English)**

DoC number	DoC revision	Technical Documentation Number
439623	02	ZBTD_WIN_484
Legal Manufacturer: Zimmer Switzerland Manufacturing GmbH Sulzerallee 8 8404 Winterthur Switzerland SRN: CH-MF-000008793		Authorized Representative: Biomet GSCC B.V. Hazeldonk 6530 4836 LD Breda The Netherlands SRN: NL-AR-000000422
Product (system) Name: NCB® System Instruments		
Classification: Class IIa, per Annex VIII, Rule 6 of Regulation (EU) 2017/745. Class Ir, per Annex VIII, Rule 6, Item 2 of Regulation (EU) 2017/745. Class I, per Annex VIII, Rule 1 of Regulation (EU) 2017/745. Product References, Basic UDI-DI, EMDN: Refer to the scope list below.		
Intended Purpose: Surgical instruments and provisionals are intended to be used by orthopedic surgeons to facilitate the implanting or explanting of specific implants described in the product-specific surgical technique. Refer to the implant specific IFU for information on the intended use, indications and contraindications of the implant. Sterilization case components are intended to facilitate the organization, identification, storage, transportation cleaning and sterilization reprocessing of instruments and provisionals. General surgical instruments are intended to facilitate surgical procedures. They can be used across multiple systems.		
Conformity Assessment Route: For class I: Article 52 (7); For class Ir: Annex IX Ch. I and III For class IIa: Annex IX, Ch. I and III, and section 4 of Ch. II		Technical Documentation Assessment Certificate/s No.: Not applicable to device classe(s) in scope of this declaration
Notified Body: BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands CE 2797 Not applicable for class I products		Reference to Common Specifications: There are no Common Specifications available which are applicable to these devices at this issue of the Declaration.

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Statement of Compliance:

This declaration of conformity is issued under the sole responsibility of the manufacturer who hereby declares that the medical device(s) specified above meet the provisions of Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council.

This declaration is supported by the EU Quality Management System Certificate (MDR 743795) issued by BSI Group The Netherlands B.V. (CE 2797) and the Quality System approval to ISO 13485 (MD 743676) issued by BSI Group The Netherlands B.V. (CE 2797). All supporting documentation is retained at the premises of the legal manufacturer.

_____	Regulatory Affairs Manager
Name	Function/Designation
_____	Winterthur, Switzerland 31-05-2022
Signature	Place and Date of Issue (DD.MM.YYYY)

The DoC is signed for, and on behalf of, the Legal Manufacturer issuing this Declaration of Conformity.

The Declaration of Conformity is signed off on behalf of the Legal Manufacturer in the English part of this document.

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Scope List:

Product ID	Product Description	EU Device Class	Classification Rule and Item	Basic UDI-DI	GMDN	EMDN
02.00024.601	NCB®-DF graphic case, lid	I	Rule 1	889024N8JC	44759	L091099
02.00024.602	NCB®-DF graphic case, base (Inox)	I	Rule 1	889024N8JC	44759	L091099
02.00024.603	NCB®-DF graphic case, module instruments	I	Rule 1	889024N8JC	44759	L091099
02.00024.604	NCB®-DF graphic case, module implants	I	Rule 1	889024N8JC	44759	L091099
02.00024.605	NCB®-DF graphic case, module screw rack	I	Rule 1	889024N8JC	44759	L091099
02.00024.606	NCB®-DF graphic case, module MIS-instruments	I	Rule 1	889024N8JC	44759	L091099
02.00024.701	NCB®-PH graphic case, cover	I	Rule 1	889024N9JE	44759	L091099
02.00024.702	NCB®-PH graphic case, base (Inox)	I	Rule 1	889024N9JE	44759	L091099
02.00024.763	NCB®-PH Graphic case, module instruments	I	Rule 1	889024N9JE	44759	L091099
02.00024.764	NCB®-PH Graphic case, module implants	I	Rule 1	889024N9JE	44759	L091099
02.00024.765	NCB®-PH Graphic case, module screw rack	I	Rule 1	889024N9JE	44759	L091099
02.00024.766	NCB®-PH Graphic case, module instruments (empty)	I	Rule 1	889024N9JE	44759	L091099
02.00024.767	NCB®-PH Graphic case, module MIS instruments	I	Rule 1	889024N9JE	44759	L091099
02.00024.768	NCB®-PH Graphic case, module MIS screw rack	I	Rule 1	889024N9JE	44759	L091099
02.00024.801	NCB®-PT graphic case, lid	I	Rule 1	889024NAJU	44759	L091099
02.00024.802	NCB®-PT graphic case, base (Inox)	I	Rule 1	889024NAJU	44759	L091099

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02.00024.803	NCB®-PT graphic case, module instruments	I	Rule 1	889024NAJU	44759	L091099
02.00024.804	NCB®-PT graphic case, module implants and cannulated instruments	I	Rule 1	889024NAJU	44759	L091099
02.00024.805	NCB®-PT graphic case, module screw rack	I	Rule 1	889024NAJU	44759	L091099
02.00024.806	NCB®-PT graphic case, module MIS-instruments	I	Rule 1	889024NAJU	44759	L091099
100.06.010	Plate bending press	I	Rule 1	889024NCJY	44759	L091001
02.00002.001	Assembly pin	Ir	Rule 6, 2 nd indent	889024LYL6	44759	L091001
02.00024.005	NCB®, measuring instrument, 110 mm	Ir	Rule 6, 2 nd indent	889024M1HT	44759	L091001
02.00024.006	NCB®, measuring instrument	Ir	Rule 6, 2 nd indent	889024M1HT	44759	L091001
02.00024.007	NCB®-PT, depth gauge, 110 mm	Ir	Rule 6, 2 nd indent	889024M1HT	44759	L091001
02.00024.010	NCB®, drill guide, ø 2.5 mm	Ir	Rule 6, 2 nd indent	889024M2HV	44759	L091001
02.00024.011	NCB®, drill guide, ø 4.3 mm	Ir	Rule 6, 2 nd indent	889024M2HV	44759	L091001
02.00024.111	NCB®, drill guide for screws (ø 4.0/4.5 mm), ø 3.3 mm	Ir	Rule 6, 2 nd indent	889024M2HV	44759	L091001
02.00024.021	NCB®-DF torque screwdriver, 6 Nm, 280 mm	Ir	Rule 6, 2 nd indent	889024M3HX	44759	L091001
02.00024.022	NCB®-PH, torque screwdriver, 3.5, 4 Nm	Ir	Rule 6, 2 nd indent	889024M3HX	44759	L091001
02.00024.023	NCB® MIS, screwdriver for femur, hexagonal, SW 3.5	Ir	Rule 6, 2 nd indent	889024M4HZ	44759	L091001
02.00024.120	NCB®, screwdriver, cannulated, short hexagon 3.5, 245 mm	Ir	Rule 6, 2 nd indent	889024M4HZ	44759	L091001

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02.00024.124	NCB®-PT, screwdriver, hexagonal, 3.5 mm	Ir	Rule 6, 2 nd indent	889024M4HZ	44759	L091001
109.01.020	Screwdriver, hexagonal, S, without holding sleeve, hexagon ø 2.5 mm	Ir	Rule 6, 2 nd indent	889024M4HZ	44759	L091001
02.00024.060	NCB®-DF, soft tissue protection sleeve, ø 10.0/8.2 mm	Ir	Rule 6, 2 nd indent	889024M7J7	44759	L091001
02.00024.090	NCB®-PT, soft tissue protection sleeve, ø 10.0 mm/8.2 mm	Ir	Rule 6, 2 nd indent	889024M7J7	44759	L091001
02.00024.062	NCB®-DF, trocar, ø 4.3 mm	Ir	Rule 6, 2 nd indent	889024M8J9	44759	L091001
02.00024.070	NCB®-DF, targeting instrument for right plates	Ir	Rule 6, 2 nd indent	889024M9JB	44759	L091001
02.00024.071	NCB®-DF, targeting instrument for left plates	Ir	Rule 6, 2 nd indent	889024M9JB	44759	L091001
02.00024.073	NCB®-DF, connection bolt for targeting instrument, 144 mm	Ir	Rule 6, 2 nd indent	889024MAJR	44759	L091001
02.00024.074	NCB®-DF, stabilization bolt for targeting instrument, 153 mm	Ir	Rule 6, 2 nd indent	889024MBJT	44759	L091001
02.00024.076	NCB®, safety lock pin for targeting device (femur)	Ir	Rule 6, 2 nd indent	889024MCJV	44759	L091001
02.00024.077	NCB®-PT, screw marker for targeting device	Ir	Rule 6, 2 nd indent	889024MDJX	44759	L091001
02.00024.080	NCB®-PT, targeting device for right plates	Ir	Rule 6, 2 nd indent	889024MEJZ	44759	L091001
02.00024.081	NCB®-PT targeting device for left plates	Ir	Rule 6, 2 nd indent	889024MEJZ	44759	L091001

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02.00024.083	NCB®-PT, connection bolt for targeting device, proximal	Ir	Rule 6, 2 nd indent	889024MFK3	44759	L091001
02.00024.084	NCB®-PT, stabilization bolt for targeting device, distal	Ir	Rule 6, 2 nd indent	889024MGK5	44759	L091001
109.02.020	Screwdriver with self-holding hexagon, S, 2.5 mm/200 mm	Ir	Rule 6, 2 nd indent	889024MHK7	44742	L091001
02.00024.091	NCB®-PT, drill guide, ø 8.2 mm/5.2 mm	Ir	Rule 6, 2 nd indent	889024MJKB	44759	L091001
02.00024.092	NCB®-PT, drill guide, ø 5.2 mm/2 mm	Ir	Rule 6, 2 nd indent	889024MJKB	44759	L091001
02.00024.192	NCB®-PT, drill guide, ø 3.3 mm/1.6 mm	Ir	Rule 6, 2 nd indent	889024MJKB	44759	L091001
02.00024.093	NCB®-PT, trocar, ø 2 mm	Ir	Rule 6, 2 nd indent	889024MKKD	44759	L091001
02.00024.116	NCB®-PH, trocar, ø 1.6 mm	Ir	Rule 6, 2 nd indent	889024MKKD	44759	L091001
02.00024.101	NCB®-PH, handle for targeting device	Ir	Rule 6, 2 nd indent	889024MLKF	44759	L091001
02.00024.103	NCB®-PH, connection screw for targeting device	Ir	Rule 6, 2 nd indent	889024MMKH	44759	L091001
02.00024.104	NCB®, fixation screw for double targeting adapter	Ir	Rule 6, 2 nd indent	889024MNKK	44759	L091001
02.00024.114	NCB®-PH, drill guide, ø 8/ø 3.3 mm	Ir	Rule 6, 2 nd indent	889024MPKP	44759	L091001
02.00024.115	NCB®-PH, drill guide, ø 3.3/1.6 mm	Ir	Rule 6, 2 nd indent	889024MPKP	44759	L091001
02.00024.223	NCB®-PH, drill guide, ø 5.0/3.0 mm, for REF 02.00024.220	Ir	Rule 6, 2 nd indent	889024MPKP	44759	L091001
02.00024.061	NCB®-DF, drill guide, ø 8.2/4.3 mm	Ir	Rule 6, 2 nd indent	889024MTKX	44759	L091001

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02.00024.121	NCB®, locking screw holder for hexagonalscrewdriver (3.5 mm)	Ir	Rule 6, 2 nd indent	889024MUKZ	44759	L091001
02.00024.202	NCB®-PH, targeting module for targeting device	Ir	Rule 6, 2 nd indent	889024MWL5	44759	L091001
02.00024.213	NCB®-PH- tissue protection sleeve ø 10.0/8.0, for REF 02.00024.202	Ir	Rule 6, 2 nd indent	889024MXL7	44759	L091001
02.00024.222	NCB®-PH, tissue protection sleeve, ø7.0/6.0 mm, for REF 02.00024.220	Ir	Rule 6, 2 nd indent	889024MXL7	44759	L091001
02.00024.214	NCB®-PH, measuring device, 70 mm	Ir	Rule 6, 2 nd indent	889024MYL9	44759	L091001
02.00024.216	NCB®-PH, depth gauge for screws (ø 3.5 mm), S	Ir	Rule 6, 2 nd indent	889024N1HW	44759	L091001
02.00024.219	NCB®-PH/PT, measuring device for cannulated screws	Ir	Rule 6, 2 nd indent	889024N1HW	44759	L091001
100.90.025	Depth gauge for screws (ø 3.5 - 4 mm), maximum 110 mm	Ir	Rule 6, 2 nd indent	889024N1HW	44759	L091001
02.00024.220	NCB®-PH, jig for 3.5 mm locking screw	Ir	Rule 6, 2 nd indent	889024N2HY	44759	L091001
02.00024.221	NCB®-PH, connection screw for REF 02.00024.220	Ir	Rule 6, 2 nd indent	889024N2HY	44759	L091001
110.06.200	Cleaning wire, ø 1.6 mm, 230 mm	Ir	Rule 6, 2 nd indent	889024NBJW	44759	L091001
100.11.115	Wire cutter for wires max. ø 1.7 mm, 165 mm	Ir	Rule 6, 2 nd indent	889024NDK2	44759	L091001
100.11.155	Wire bending forceps, 140 mm	Ir	Rule 6, 2 nd indent	889024NEK4	44759	L091001

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100.40.035	Drill guide for screws (ø 3.5/4 mm), double, ø 2.5 mm	Ir	Rule 6, 2 nd indent	889024NFK6	44759	L091001
100.90.005	Screw forceps, self-holding	Ir	Rule 6, 2 nd indent	889024NGK8	44759	L091001
02.00024.001	NCB®, drill bit, ø 4.3 mm, 145 mm	Ila	Rule 6	889024LZL8	44759	L091001
02.00024.002	NCB®, drill bit, ø 4.3 mm, 195 mm	Ila	Rule 6	889024LZL8	44759	L091001
02.00024.003	NCB®-DF, drill bit, 4.3, length 300 mm	Ila	Rule 6	889024LZL8	44759	L091001
02.00024.024	NCB®, screwdriver shaft, hexagonal, SW 3.5	Ila	Rule 6	889024M5J3	44759	L091001
02.00024.027	NCB®-PT, screwdriver shaft, hexagonal, 3.5 mm	Ila	Rule 6	889024M5J3	44759	L091001
02.00024.040	NCB®-PT, tap with quick coupling, ø 4 mm	Ila	Rule 6	889024M6J5	44759	L091001
02.00024.050	NCB®, taps for quick coupling, ø 5 mm	Ila	Rule 6	889024M6J5	44759	L091001
02.00024.051	NCB®-DF, taps for quick coupling, ø 5 mm, 250 mm	Ila	Rule 6	889024M6J5	44759	L091001
108.01.035	Countersink with quick coupling for screws (ø 3.5 + 4 mm)	Ila	Rule 6	889024MQKR	44491	L091001
02.00024.117	NCB®, drill bit with quick coupling, cannulated, ø 3.3 mm, 195 mm	Ila	Rule 6	889024MRKT	44759	L091001
02.00024.233	NCB®-PT, drill bit, cannulated, ø 3.3 mm, with quick coupling, 195 mm	Ila	Rule 6	889024MRKT	44759	L091001

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02.00024.118	NCB®, drill bit with quick coupling, ø 3.3 mm, 195 mm	Ila	Rule 6	889024MSKV	44759	L091001
02.00024.215	NCB®-PH, MIS drill bit with quick coupling, ø 3.3 mm	Ila	Rule 6	889024MSKV	44759	L091001
02.00024.125	NCB®-PT, drill bit with quick coupling, ø 2.5 mm	Ila	Rule 6	889024MVL3	44759	L091001
02.00024.133	NCB®-PT, drill bit with quick coupling, ø 3.3 mm	Ila	Rule 6	889024MVL3	44759	L091001
02.00024.143	NCB®-PT, drill bit with quick coupling, ø 4.3 mm	Ila	Rule 6	889024MVL3	44759	L091001
103.25.180	Drill bit with quick coupling, 2-fluted, ø 2.5 mm, 154/180 mm	Ila	Rule 6	889024MZLB	44491	L091001
02.00024.350	NCB®, periprosthetic femur plate, provisional, proximal, right, 15/18 hole plates	Ila	Rule 6	889024N3J2	44759	L091099
02.00024.351	NCB®, periprosthetic femur plate, provisional, proximal, left, 15/18 hole plates	Ila	Rule 6	889024N3J2	44759	L091099
02.00024.352	NCB®, periprosthetic femur plate, provisional, proximal, right, 9/12 hole plates	Ila	Rule 6	889024N3J2	44759	L091099
02.00024.353	NCB®, periprosthetic femur plate, provisional, proximal, left, 9/12 hole plates	Ila	Rule 6	889024N3J2	44759	L091099
02.00024.354	NCB®, periprosthetic femur plate, provisional, distal, right, 15/18 hole plates	Ila	Rule 6	889024N4J4	44759	L091099

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02.00024.355	NCB®, periprosthetic femur plate, provisional, distal, left, 15/18 hole plates	Ila	Rule 6	889024N4J4	44759	L091099
02.00024.356	NCB®, periprosthetic femur plate, provisional, distal, right, 9/12 hole plates	Ila	Rule 6	889024N4J4	44759	L091099
02.00024.357	NCB®, periprosthetic femur plate, provisional, distal, left, 9/12 hole plates	Ila	Rule 6	889024N4J4	44759	L091099
02.00024.358	NCB®, femur shaft plate, provisional, curved, 10/12/14 hole plates	Ila	Rule 6	889024N5J6	44759	L091099
02.00024.401	NCB®, shaft plate, provisional, straight, narrow, 8/10/12	Ila	Rule 6	889024N6J8	44759	L091099
02.00024.402	NCB®, shaft plate, provisional, straight, narrow, 14/16/18	Ila	Rule 6	889024N6J8	44759	L091099
02.00024.411	NCB®-PP, trochanter plate, provisional, right, narrow	Ila	Rule 6	889024N7JA	44759	L091099
02.00024.412	NCB®-PP, trochanter plate, provisional, left, narrow	Ila	Rule 6	889024N7JA	44759	L091099
02.00024.413	NCB®-PP, trochanter plate, provisional, right, wide	Ila	Rule 6	889024N7JA	44759	L091099
02.00024.414	NCB®-PP, trochanter plate, provisional, left, wide	Ila	Rule 6	889024N7JA	44759	L091099

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Declaration of Conformity Revision History:

Revision	Date	Change Number	Description
00	21-May-2021	500000044496	Initial creation
01	See signature page	500000044496	Update to include Class Ir and IIa instruments
02	See signature page	500000044496	Update due to CMR labeling

The revision history of the declaration of conformity is kept in the English part only.