

EC Declaration of Conformity

Manufacturer: Zimmer GmbH
Sulzerallee 8
8404 Winterthur
Switzerland

Product (System) Name: **NCB Polyaxial Locking Plate System (sterile)**

Scope: See scope list below

Classification: Class IIb, in accordance to rule 8, Annex IX of the Council Directive 93/42/EEC concerning medical devices.

Conformity Assessment Route: Zimmer GmbH uses the following procedures for the CE-marking of this product according to the Directive 93/42/EEC:
Class IIb: EC Conformity Declaration according to Annex II.3

GMDN Code: 61688, Internal orthopaedic fixation system, plate/screw, non-bioabsorbable, sterile

Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands
Identification Number: CE 2797

European Authorized Representative: Biomet GSCC B.V.
Hazeldonk 6530
4836 LD Breda
The Netherlands

We hereby declare that the medical device(s) specified above meet the provisions of the Council Directive No. 93/42/EEC. This declaration is supported by the EC Full Quality Assurance Certificate CE 516222 and the Quality System approval to ISO 13485 issued by BSI. All supporting documentation is retained at the premises of the manufacturer.

21. MAI 2021

Date (dd.mm.yyyy)

Regulatory Affairs Manager



Scope List

Article number	Product name	Class
02.02150.014	NCB®, cortical screw, 5.0 mm, 14 mm	IIb
02.02150.016	NCB®, cortical screw, 5.0 mm, 16 mm	IIb
02.02150.018	NCB®, cortical screw, 5.0 mm, 18 mm	IIb
02.02150.020	NCB®, cortical screw, 5.0 mm, 20 mm	IIb
02.02150.022	NCB®, cortical screw, 5.0 mm, 22 mm	IIb
02.02150.024	NCB®, cortical screw, 5.0 mm, 24 mm	IIb
02.02150.026	NCB®, cortical screw, 5.0 mm, 26 mm	IIb
02.02150.028	NCB®, cortical screw, 5.0 mm, 28 mm	IIb
02.02150.030	NCB®, cortical screw, 5.0 mm, 30 mm	IIb
02.02150.032	NCB®, cortical screw, 5.0 mm, 32 mm	IIb
02.02150.034	NCB®, cortical screw, 5.0 mm, 34 mm	IIb
02.02150.036	NCB®, cortical screw, 5.0 mm, 36 mm	IIb
02.02150.038	NCB®, cortical screw, 5.0 mm, 38 mm	IIb
02.02150.040	NCB®, cortical screw, 5.0 mm, 40 mm	IIb
02.02150.042	NCB®, cortical screw, 5.0 mm, 42 mm	IIb
02.02150.044	NCB®, cortical screw, 5.0 mm, 44 mm	IIb
02.02150.046	NCB®, cortical screw, 5.0 mm, 46 mm	IIb
02.02150.048	NCB®, cortical screw, 5.0 mm, 48 mm	IIb
02.02150.050	NCB®, cortical screw, 5.0 mm, 50 mm	IIb
02.02150.055	NCB®, cortical screw, 5.0 mm, 55 mm	IIb
02.02150.060	NCB®, cortical screw, 5.0 mm, 60 mm	IIb
02.02150.065	NCB®, cortical screw, 5.0 mm, 65 mm	IIb
02.02150.070	NCB®, cortical screw, 5.0 mm, 70 mm	IIb
02.02150.075	NCB®, cortical screw, 5.0 mm, 75 mm	IIb
02.02150.080	NCB®, cortical screw, 5.0 mm, 80 mm	IIb
02.02150.085	NCB®, cortical screw, 5.0 mm, 85 mm	IIb
02.02150.090	NCB®, cortical screw, 5.0 mm, 90 mm	IIb
02.02150.095	NCB®, cortical screw, 5.0 mm, 95 mm	IIb
02.02150.100	NCB®, cortical screw, 5.0 mm, 100 mm	IIb
02.02150.300	NCB® locking cap	IIb
02.02150.310	NCB® blind screw insert	IIb



Article number	Product name	Class
02.02150.311	NCB® spacer, 1 mm	IIb
02.02150.312	NCB® spacer, 2 mm	IIb
02.02150.313	NCB® spacer, 3 mm	IIb
02.02152.050	NCB® cancellous screw, ø 5.0 mm, 32 mm, 50 mm	IIb
02.02152.055	NCB® cancellous screw, ø 5.0mm, 32 mm, 55 mm	IIb
02.02152.060	NCB® cancellous screw, ø 5.0 mm, 32 mm, 60 mm	IIb
02.02152.065	NCB® cancellous screw, ø 5.0 mm, 32 mm, 65 mm	IIb
02.02152.070	NCB® cancellous screw, ø 5.0mm, 32 mm, 70 mm	IIb
02.02152.075	NCB® cancellous screw, ø 5.0 mm, 32 mm, 75 mm	IIb
02.02152.080	NCB® cancellous screw, ø 5.0 mm, 32 mm, 80 mm	IIb
02.02152.085	NCB® cancellous screw, ø 5.0 mm, 32 mm, 85 mm	IIb
02.02152.090	NCB® cancellous screw, ø 5.0 mm, 32 mm, 90 mm	IIb
02.02152.095	NCB® cancellous screw, ø 5.0 mm, 32 mm, 95 mm	IIb
02.02152.100	NCB® cancellous screw, ø 5.0 mm, 32 mm, 100 mm	IIb
02.02155.014	NCB®, cortical screw, self-tapping, ø 4.0, 14 mm	IIb
02.02155.016	NCB®, cortical screw, self-tapping, ø 4.0, 16 mm	IIb
02.02155.018	NCB®, cortical screw, self-tapping, ø 4.0, 18 mm	IIb
02.02155.020	NCB®, cortical screw, self-tapping, ø 4.0, 20 mm	IIb
02.02155.022	NCB®, cortical screw, self-tapping, ø 4.0, 22 mm	IIb
02.02155.024	NCB®, cortical screw, self-tapping, ø 4.0, 24 mm	IIb
02.02155.026	NCB®, cortical screw, self-tapping, ø 4.0, 26 mm	IIb
02.02155.028	NCB®, cortical screw, self-tapping, ø 4.0, 28 mm	IIb
02.02155.030	NCB®, cortical screw, self-tapping, ø 4.0, 30 mm	IIb
02.02155.032	NCB®, cortical screw, self-tapping, ø 4.0, 32 mm	IIb
02.02155.034	NCB®, cortical screw, self-tapping, ø 4.0, 34 mm	IIb
02.02155.036	NCB®, cortical screw, self-tapping, ø 4.0, 36 mm	IIb
02.02155.038	NCB®, cortical screw, self-tapping, ø 4.0, 38 mm	IIb
02.02155.040	NCB®, cortical screw, self-tapping, ø 4.0, 40 mm	IIb
02.02155.042	NCB®, cortical screw, self-tapping, ø 4.0, 42 mm	IIb
02.02155.044	NCB®, cortical screw, self-tapping, ø 4.0, 44 mm	IIb
02.02155.046	NCB®, cortical screw, self-tapping, ø 4.0, 46 mm	IIb
02.02155.048	NCB®, cortical screw, self-tapping, ø 4.0, 48 mm	IIb

Article number	Product name	Class
02.02155.050	NCB®, cortical screw, self-tapping, ø 4.0, 50 mm	IIb
02.02155.055	NCB®, cortical screw, self-tapping, ø 4.0, 55 mm	IIb
02.02155.060	NCB®, cortical screw, self-tapping, ø 4.0, 60 mm	IIb
02.02155.065	NCB®, cortical screw, self-tapping, ø 4.0, 65 mm	IIb
02.02155.070	NCB®, cortical screw, self-tapping, ø 4.0, 70 mm	IIb
02.02155.075	NCB®, cortical screw, self-tapping, ø 4.0, 75 mm	IIb
02.02155.080	NCB®, cortical screw, self-tapping, ø 4.0, 80 mm	IIb
02.02155.085	NCB®, cortical screw, self-tapping, ø 4.0, 85 mm	IIb
02.02155.090	NCB®, cortical screw, self-tapping, ø 4.0, 90 mm	IIb
02.02155.095	NCB®, cortical screw, self-tapping, ø 4.0, 95 mm	IIb
02.02155.100	NCB®, cortical screw, self-tapping, ø 4.0 mm, 100 mm	IIb
02.02157.014	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 14 mm	IIb
02.02157.016	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 16 mm	IIb
02.02157.018	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 18 mm	IIb
02.02157.020	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 20 mm	IIb
02.02157.022	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 22 mm	IIb
02.02157.024	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 24 mm	IIb
02.02157.026	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 26 mm	IIb
02.02157.028	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 28 mm	IIb
02.02157.030	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 30 mm	IIb
02.02157.032	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 32 mm	IIb
02.02157.034	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 34 mm	IIb
02.02157.036	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 36 mm	IIb
02.02157.038	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 38 mm	IIb
02.02157.040	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 40 mm	IIb
02.02157.042	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 42 mm	IIb
02.02157.044	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 44 mm	IIb
02.02157.046	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 46 mm	IIb
02.02157.048	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 48 mm	IIb
02.02157.050	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 50 mm	IIb
02.02157.055	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 55 mm	IIb
02.02157.060	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 60 mm	IIb



Article number	Product name	Class
02.02157.065	NCB®, cortical screw, cannulated, ø 4.0, self-drill, 65 mm	IIb
02.02158.030	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 30 mm	IIb
02.02158.032	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 32 mm	IIb
02.02158.034	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 34 mm	IIb
02.02158.036	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 36 mm	IIb
02.02158.038	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 38 mm	IIb
02.02158.040	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 40 mm	IIb
02.02158.042	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 42 mm	IIb
02.02158.044	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 44 mm	IIb
02.02158.046	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 46 mm	IIb
02.02158.048	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 48 mm	IIb
02.02158.050	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 50 mm	IIb
02.02158.055	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 55 mm	IIb
02.02158.060	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 60 mm	IIb
02.02158.065	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 65 mm	IIb
02.02158.070	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 70 mm	IIb
02.02158.075	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 75 mm	IIb
02.02158.080	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 80 mm	IIb
02.02158.085	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 85 mm	IIb
02.02158.090	NCB® cancellous screw, cannulated, ø 4.5, self-drill, 90 mm	IIb
02.02159.030	NCB® cancellous screw, ø 4.5 mm, fully threaded, 30 mm	IIb
02.02159.032	NCB® cancellous screw, ø 4.5 mm, fully threaded, 32 mm	IIb
02.02159.034	NCB® cancellous screw, ø 4.5 mm, fully threaded, 34 mm	IIb
02.02159.036	NCB® cancellous screw, ø 4.5 mm, fully threaded, 36 mm	IIb
02.02159.038	NCB® cancellous screw, ø 4.5 mm, fully threaded, 38 mm	IIb
02.02159.040	NCB® cancellous screw, ø 4.5 mm, fully threaded, 40 mm	IIb
02.02159.042	NCB® cancellous screw, ø 4.5 mm, fully threaded, 42 mm	IIb
02.02159.044	NCB® cancellous screw, ø 4.5 mm, fully threaded, 44 mm	IIb
02.02159.046	NCB® cancellous screw, ø 4.5 mm, fully threaded, 46 mm	IIb
02.02159.048	NCB® cancellous screw, ø 4.5 mm, fully threaded, 48 mm	IIb
02.02159.050	NCB® cancellous screw, ø 4.5 mm, fully threaded, 50 mm	IIb
02.02159.055	NCB® cancellous screw, ø 4.5 mm, fully threaded, 55 mm	IIb



Article number	Product name	Class
02.02159.060	NCB® cancellous screw, ø 4.5 mm, fully threaded, 60 mm	IIb
02.02159.065	NCB® cancellous screw, ø 4.5 mm, fully threaded, 65 mm	IIb
02.02160.030	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 30 mm	IIb
02.02160.032	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 32 mm	IIb
02.02160.034	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 34 mm	IIb
02.02160.036	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 36 mm	IIb
02.02160.038	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 38 mm	IIb
02.02160.040	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 40 mm	IIb
02.02160.042	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 42 mm	IIb
02.02160.044	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 44 mm	IIb
02.02160.046	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 46 mm	IIb
02.02160.048	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 48 mm	IIb
02.02160.050	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 50 mm	IIb
02.02160.055	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 55 mm	IIb
02.02160.060	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 60 mm	IIb
02.02160.065	NCB® cancellous screw, cannulated, ø 4.5 mm, fully threaded, 65 mm	IIb
02.02260.005	NCB®-DF plate, right, 5 holes, 167 mm	IIb
02.02260.009	NCB®-DF plate, right, 9 holes, 246 mm	IIb
02.02260.013	NCB®-DF plate, right, 13 holes, 324 mm	IIb
02.02260.105	NCB®-DF plate, left, 5 holes, 167 mm	IIb
02.02260.109	NCB®-DF plate, left, 9 holes, 246 mm	IIb
02.02260.113	NCB®-DF plate, left, 13 holes, 324 mm	IIb
02.02261.005	NCB®-PT, 2 hole tibial plate, lateral, proximal, 5 hole, right, 132 mm	IIb
02.02261.007	NCB®-PT, 2 hole tibial plate, lateral, proximal, 7 hole, right, 172 mm	IIb
02.02261.009	NCB®-PT, 2 hole tibial plate, lateral, proximal, 9 hole, right, 212 mm	IIb
02.02261.105	NCB®-PT, 2 hole tibial plate, lateral, proximal, 5 hole, left, 132 mm	IIb
02.02261.107	NCB®-PT, 2 hole tibial plate, lateral, proximal, 7 hole, left, 172 mm	IIb
02.02261.109	NCB®-PT, 2 hole tibial plate, lateral, proximal, 9 hole, left, 212 mm	IIb
02.02261.203	NCB®-PT, 3 hole tibial plate, lateral, proximal, 3 hole, right, 92mm	IIb
02.02261.205	NCB®-PT, 3 hole tibial plate, lateral, proximal, 5 hole, right, 132 mm	IIb
02.02261.207	NCB®-PT, 3 hole tibial plate, lateral, proximal, 7 hole, right, 172 mm	IIb
02.02261.209	NCB®-PT, 3 hole tibial plate, lateral, proximal, 9 hole, right, 212 mm	IIb

Article number	Product name	Class
02.02261.213	NCB®-PT, 3 hole tibial plate, lateral, proximal, 13 hole, right, 292 mm	IIb
02.02261.303	NCB®-PT, 3 hole tibial plate, lateral, proximal, 3 hole, left, 92mm	IIb
02.02261.305	NCB®-PT, 3 hole tibial plate, lateral, proximal, 5 hole, left, 132 mm	IIb
02.02261.307	NCB®-PT, 3 hole tibial plate, lateral, proximal, 7 hole, left, 172 mm	IIb
02.02261.309	NCB®-PT, 3 hole tibial plate, lateral, proximal, 9 hole, left, 212 mm	IIb
02.02261.313	NCB®-PT, 3 hole tibial plate, lateral, proximal, 13 hole, left, 292 mm	IIb
02.02262.101	NCB® T.minus plate, 7 holes	IIb
02.02262.104	NCB®-PH plate, 4 holes, with proximal locked holes, 80 mm	IIb
02.02262.105	NCB®-PH plate, 5 holes, with proximal locked holes, 93 mm	IIb
02.02262.107	NCB®-PH plate, 7 holes, with proximal locked holes, 117 mm	IIb

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