

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

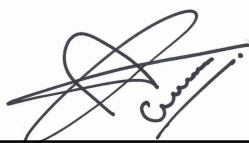
No.**CE 544417****Issued To:**

**Zimmer GmbH
Sulzerallee 8
Winterthur
8404
Switzerland**

In respect of:**Ceramic Femoral Heads**

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: 2009-01-26**Date: 2019-03-04****Expiry Date: 2024-01-25**

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Supplementary Information to CE 544417

Issued To:

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Catalog No.	Description
BioloX® delta Ceramic Femoral Head	
00-8775-028-01	BioloX® delta Head 12/14, 28 x -3.5
00-8775-028-02	BioloX® delta Head 12/14, 28 x 0
00-8775-028-03	BioloX® delta Head 12/14, 28 x +3.5
00-8775-032-01	BioloX® delta Head 12/14, 32 x -3.5
00-8775-032-02	BioloX® delta Head 12/14, 32 x 0
00-8775-032-03	BioloX® delta Head 12/14, 32 x +3.5
00-8775-032-04	BioloX® delta Head 12/14, 32 x +7
00-8775-036-01	BioloX® delta Head 12/14, 36 x -3.5
00-8775-036-02	BioloX® delta Head 12/14, 36 x 0
00-8775-036-03	BioloX® delta Head 12/14, 36 x +3.5
00-8775-036-04	BioloX® delta Head 12/14, 36 x +7
00-8775-040-01	BioloX® delta Head 12/14, 40 x -3.5
00-8775-040-02	BioloX® delta Head 12/14, 40 x 0
00-8775-040-03	BioloX® delta Head 12/14, 40 x +3.5
00-8775-040-04	BioloX® delta Head 12/14, 40 x +7
BioloX® OPTION Head System (Head + Adapter)	
00-8777-028-01	BioloX® OPTION Hd/Adpt, 12/14, 28 x -3.0

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
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00-8777-028-02	Biolox® OPTION Hd/Adpt, 12/14, 28 x 0
00-8777-028-03	Biolox® OPTION Hd/Adpt, 12/14, 28 x +3.5
00-8777-028-04	Biolox® OPTION Hd/Adpt, 12/14, 28 x +7
00-8777-032-01	Biolox® OPTION Hd/Adpt, 12/14, 32 x -3.0
00-8777-032-02	Biolox® OPTION Hd/Adpt, 12/14, 32 x 0
00-8777-032-03	Biolox® OPTION Hd/Adpt, 12/14, 32 x +3.5
00-8777-032-04	Biolox® OPTION Hd/Adpt, 12/14, 32 x +7
00-8777-036-01	Biolox® OPTION Hd/Adpt, 12/14, 36 x -3.0
00-8777-036-02	Biolox® OPTION Hd/Adpt, 12/14, 36 x 0
00-8777-036-03	Biolox® OPTION Hd/Adpt, 12/14, 36 x +3.5
00-8777-036-04	Biolox® OPTION Hd/Adpt, 12/14, 36 x +7
00-8777-040-01	Biolox® OPTION Hd/Adpt, 12/14, 40 x -3.0
00-8777-040-02	Biolox® OPTION Hd/Adpt, 12/14, 40 x 0
00-8777-040-03	Biolox® OPTION Hd/Adpt, 12/14, 40 x +3.5
00-8777-040-04	Biolox® OPTION Hd/Adpt, 12/14, 40 x +7
00-8777-044-01	Biolox® OPTION Hd/Adpt, 12/14, 44 x -3.0
00-8777-044-02	Biolox® OPTION Hd/Adpt, 12/14, 44 x 0
00-8777-044-03	Biolox® OPTION Hd/Adpt, 12/14, 44 x +3.5

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00-8777-044-04	Bilox® OPTION Hd/Adpt, 12/14, 44 x +7
00-8777-048-01	Bilox® OPTION Hd/Adpt, 12/14, 48 x -3.0
00-8777-048-02	Bilox® OPTION Hd/Adpt, 12/14, 48 x 0
00-8777-048-03	Bilox® OPTION Hd/Adpt, 12/14, 48 x +3.5
00-8777-048-04	Bilox® OPTION Hd/Adpt, 12/14, 48 x +7
00-8778-028-01	Bilox® OPTION Hd/Adpt, 8/10, 28 x -3.0
00-8778-028-02	Bilox® OPTION Hd/Adpt, 8/10, 28 x 0
00-8778-028-03	Bilox® OPTION Hd/Adpt, 8/10, 28 x +4.0
00-8778-032-01	Bilox® OPTION Hd/Adpt, 8/10, 32 x -3.0
00-8778-032-02	Bilox® OPTION Hd/Adpt, 8/10, 32 x 0
00-8778-032-03	Bilox® OPTION Hd/Adpt, 8/10, 32 x +4.0
00-8778-036-01	Bilox® OPTION Hd/Adpt, 8/10, 36 x -3.0
00-8778-036-02	Bilox® OPTION Hd/Adpt, 8/10, 36 x 0
00-8778-036-03	Bilox® OPTION Hd/Adpt, 8/10, 36 x +4.0
Cerasul® Ceramic Femoral Head	
407.0101	CERASUL® Head 28 / -3.5 'S' 12/14
407.0102	CERASUL® Head 28 / 0 'M' 12/14
407.0103	CERASUL® Head 28 / +3.5 'L' 12/14

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Catalog No.	Description
Sulox™ Ceramic Femoral Head	
17.28.05	Sulox™-Head 28/-3.5 "S" 12/14
17.28.06	Sulox™-Head 28/0 "M" 12/14
17.28.07	Sulox™-Head 28/+3.5 "L" 12/14
01.01202.285	Sulox™ Head 28/-3.5 'S' 8/10
01.01202.286	Sulox™ Head 28/0 'M' 8/10
01.01202.287	Sulox™ Head 28/+3.5 'L' 8/10
17.32.05	Sulox™-Head 32/-3.5 "S" 12/14
17.32.06	Sulox™-Head 32/0 "M" 12/14
17.32.07	Sulox™-Head 32/+3.5 "L" 12/14

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Date	Reference Number	Action
26 January 2009	10100540	First issue.
7 April 2011	10121420	Addition of product codes for BioloX Option Head sizes 44mm and 48mm. Change in the intended use regarding the allowable stem taper conditions for BioloX Option Heads in revision cases. Change in sterile packaging for BioloX delta (size 28mm, 32mm, 36mm only), BioloX Forte, Cerasul and Sulox heads.
12 March 2012	10130388	Packaging amendment for BioloX® delta head part numbers 00-8775-040-01 - 00-8775-040-04. Extension of shelf life from 5 years to 10 years.
18 April 2013	10140741	Addition of Metoxit AG as manufacturing subcontractor for ceramic femoral heads.
21 January 2014	10142065	Certification Renewal. Removal of BioloX Option 8/10 taper 40 mm Ceramic Heads.
18 December 2014	10152109	Approval of new finishing manufacturing area for the final cleaning and packing of specific identified devices.

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Date	Reference Number	Action
28 June 2016	10161291	Compatibility of ceramic femoral head product codes 00-877x-028-0y (x = 5, 7 or 8 and y = 1, 2, 3 or 4) and 12.28.0x (x = 5, 6, 7) expanded to include acetabular cups and liners (P0460Pxx, P04630xx, P04610xx, P0461Pxx, P0464Hxx, P05600xx, P05610xx, P0560Exx, where xx = 44 – 70) listed on GMED certificate CE 8972.
19 August 2016	10160527	Expansion of compatibility of Ceramic femoral heads (product codes 00-877x-028-0y, 12.28.0x, 17.28.0x, 01.01202.28x) to include compatibility with Biomet Active Articulation E1 Hip bearing components listed on CE 578106 (product codes 01000099x, EP-2001xx, XL-2001xx).
19 September 2016	10162318	Scope expansion, to include compatibility of BioloX delta femoral head product codes 00-877x-0yy-0z (x = 5, 7, 8; yy = 28, 32, 36, 40; z = 1, 2, 3, 4), BioloX forte femoral head product codes 12.xx.0y (xx = 28, 32; y = 5, 6, 7), 12/14 Sulox femoral head product codes 17.xx.0y (xx = 28, 32; y = 5, 6, 7), 8/10 Sulox product codes 01.01202.28x (x = 5, 6, 7) with CE 562390 EXCEED ABT product codes AR-xyyyzz (xx = 10, 11, 12; yy = 28, 32; zz = 48 – 60) and EP-xyyyzz (xx = 10, 11, 12; yy = 28, 32, 36, 40; zz = 46 – 60).
30 January 2017	10162401	Approval of packaging change for Tyvek® 1073B lidstock packaging material for specified product codes.

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Date	Reference Number	Action
27 June 2017	8426635	<p>The ceramic femoral heads listed on the certificate were approved for compatibility with:</p> <ul style="list-style-type: none"> • Biomet G7 UHMWPE (ArComXL and E1) liners listed on Biomet Orthopedics Design Examination certificate CE 578106 with the exception of all Cerasul heads and all Sulox heads and the 44 mm Biolox OPTION heads and 48 mm Biolox OPTION heads; excluding all Freedom Constrained liners and Active Articulation Hip bearings listed on CE 578106. • Biomet G7 Ceramic Liners listed on Biomet UK Limited Design Examination certificate CE 577823; excluding Biolox® forte Ceramic Femoral Heads* <p>*the Biolox® forte Ceramic Femoral Heads are only compatible with Biomet G7 UHMWPE (ArComXL and E1) liners listed on Biomet Orthopedics Design Examination certificate CE 578106.</p>
28 September 2017	8677837	Approval of new finishing manufacturing area for final cleaning and packing of Biolox OPTION femoral heads.
25 January 2019	9643076	<p>Certificate renewal.</p> <p>Removal of product codes 12.28.05, 12.28.06, 12.28.07, 12.32.05, 12.32.06, 12.32.07.</p> <p>MR compatibility information added to the information for use (IFU).</p>
Current	7781060	Traceable to NB 0086.

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