

DECLARATION OF CONFORMITY FOR PPE



Form No : ZPC 1.2100/H

Revision : 02

Declaration Number : 087-2

DECLARATION OF CONFORMITY

Legal Manufacturer:

Zimmer Surgical, Inc.
200 West Ohio Avenue
Dover, Ohio 44622

Notified Body Information:

BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam
Netherlands

EC Representative:

Biomet GSCC BV
Hazeldonk 6530
4836 LD Breda
The Netherlands



Identification Number: 2797

Conformity Assessment Route:

Annex V

The manufacturer identified above, or his authorized representative established in the Community, declares that the new PPE described above is in conformity with the provisions of Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard No EN 166:2001 (for the PPE referred to in Article 8(3)) is identical to the PPE which is the subject of EC certificate of conformity CE 700816 issued by,

*BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9 1066 EP
Amsterdam
Netherlands*

is subject to the procedure set out in Annex V of Regulation (EU) 2016/425 under the supervision of the approved body noted above.

References:

CE-Certificate Number: CE 700816

Tech File Number: 087

 16 Dec 2020
Signature and date

Jennifer Everett, Regulatory Affairs Associate Director

Name and Title

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Part Number	Description		
00992000100	SURGICAL HELMET	10/3/2019	Class I
00992000200	SURGICAL HELMET WITH LIGHT	10/3/2019	Class I
00992040112	SURGICAL HOOD	10/3/2019	Class I (sterile)
00992041110	ZIPPERED SURGICAL TOGA LARGE	10/3/2019	Class I (sterile)
00992041210	ZIPPERED SURGICAL TOGA XL	10/3/2019	Class I (sterile)
00992041310	ZIPPERED SURGICAL TOGA 2XL	10/3/2019	Class I (sterile)
00992041410	ZIPPERED SURGICAL TOGA 3XL	10/3/2019	Class I (sterile)
00992000500	SURGICAL HELMET W/LOCK	00992000500	Class I
00992000600	SURGICAL HELMET LED W/LOCK	00992000600	Class I

Revision History:

Revision No.	Revision Description	Change Notice No.
00 (Original)	Initial Release	CN 23566
01	<ul style="list-style-type: none"> Updated to new template which removed reference to Applied Standards. Updated Notified Body Information 	CN 23968
02	<ul style="list-style-type: none"> Added Surgical Helmets with Lock, part numbers 00992000500 and 00992000600 Updated EC Rep information to GSCC 	CN 24226