PRODUCER OF SPECIAL ALLOYS SINCE 1975

Mesa di Sala Giacomo & C. s.n.c.
Via dell'Artigianato, 35/37 - 25039 Travagliato (BS) ITALIA / Tel. +39 030 6863251 - Fax +39 030 6863252
info@mesaitalia.it | sales@mesaitalia.it | www.mesaitalia.it
C.F./Partita IVA - VAT IT00623390176 - N° R.E.A. BS 205429

Declaration of conformity N° 1901298/1

The undersigned company MESA di Sala Giacomo & C. S.n.c. located in via dell'Artigianato 35/37, Travagliato (BS) manufacturer of the following medical device:

Name	MAGNUM SOLARE - DISC PLAIN Ø98.5x10mm - Box1 - LM - MD
Destination	Alloy for ceramic
Shape / Drawing	DISC PLAIN Ø98.5x10mm
Batch nr	10734
Production date	18/09/2019
Quantity	10,000 NR
Customer	Digital Dental Solutions GmbH

Kind of alloy	Standards applied
Alloy for ceramic	ISO 9693-1:2012; ISO 22674:2016
Alloy for prosthesis	ISO 22674:2016
Alloy for welding	ISO 9333:2006
Alloy for bridges and crowns	ISO 22674:2016

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Declaration of conformity N° 1901298/1

Declares taking full liability that

1 - The above mentioned medical device fullfills the essential applicable requirements of Directive 93/42/CEE Annexe I concerning medical devices (harmonized with the legislative decree D.Lgs. 46/97) and all its subsequent amendments.

2 - The above mentioned medical device has been identified to belong to class IIa.

3 - The above mentioned medical device is suitable to be commercialized and it is merchandised as NON-STERILE.

4 - The above mentioned medical device is intended to be used in preparation of dental prostheses by professional operators (prosthodontists).

5 - MESA's quality system has been approved according to Directive 93/42/CEE Annex II, point 4 excluded, by TÜV SUD PRODUCT SERVICE GMBH, notified body n°0123, located in Ridlerstraße 65 – 80339 München - Germany, trough certificate n° G1 17 07 96204 004 expiring on 2023/01/16;

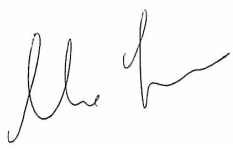
6 - MESA's quality system complies with standard UNI CEI EN ISO 13485:2016 (certificate n° Q5 096204 0005 Rev. 00 expiring on 2021/12/03); UNI CEI EN ISO 9001:2015;

7 - Other directives / standards: UNI CEI EN 1041:2013; UNI CEI EN ISO 15223-1:2012; UNI CEI EN ISO 14971:2012.

The current declaration will be stored for 15 years by the company management, in the person of Giacomo Sala.

Travagliato, 27 settembre 2019

Giacomo Sala
Managing Director



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Declaration of conformity N° 1901298/2

The undersigned company MESA di Sala Giacomo & C. S.n.c. located in via dell'Artigianato 35/37, Travagliato (BS) manufacturer of the following medical device:

Name	MAGNUM SOLARE - DISC CUT Ø98.5x12mm - Box1 - LM - MD
Destination	Alloy for ceramic
Shape / Drawing	DISC CUT Ø98.5x12mm
Batch nr	10734
Production date	18/09/2019
Quantity	15,000 NR
Customer	Digital Dental Solutions GmbH

Kind of alloy	Standards applied
Alloy for ceramic	ISO 9693-1:2012; ISO 22674:2016
Alloy for prosthesis	ISO 22674:2016
Alloy for welding	ISO 9333:2006
Alloy for bridges and crowns	ISO 22674:2016

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Declaration of conformity N° 1901298/2

Declares taking full liability that

1 - The above mentioned medical device fullfills the essential applicable requirements of Directive 93/42/CEE Annexe I concerning medical devices (harmonized with the legislative decree D.Lgs. 46/97) and all its subsequent amendments.

2 - The above mentioned medical device has been identified to belong to class IIa.

3 - The above mentioned medical device is suitable to be commercialized and it is merchandised as NON-STERILE.

4 - The above mentioned medical device is intended to be used in preparation of dental prostheses by professional operators (prosthodontists).

5 - MESA's quality system has been approved according to Directive 93/42/CEE Annex II, point 4 excluded, by TÜV SUD PRODUCT SERVICE GMBH, notified body n°0123, located in Ridlerstraße 65 – 80339 München - Germany, trough certificate n° G1 17 07 96204 004 expiring on 2023/01/16;

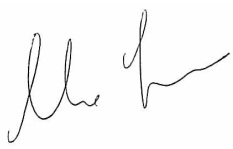
6 - MESA's quality system complies with standard UNI CEI EN ISO 13485:2016 (certificate n° Q5 096204 0005 Rev. 00 expiring on 2021/12/03); UNI CEI EN ISO 9001:2015;

7 - Other directives / standards: UNI CEI EN 1041:2013; UNI CEI EN ISO 15223-1:2012; UNI CEI EN ISO 14971:2012.

The current declaration will be stored for 15 years by the company management, in the person of Giacomo Sala.

Travagliato, 27 settembre 2019

Giacomo Sala
Managing Director



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Declaration of conformity N° 1901298/3

The undersigned company MESA di Sala Giacomo & C. S.n.c. located in via dell'Artigianato 35/37, Travagliato (BS) manufacturer of the following medical device:

Name	MAGNUM SOLARE - DISC CUT Ø98.5x13.5mm - Box1 - LM - MD
Destination	Alloy for ceramic
Shape / Drawing	DISC CUT Ø98.5x13.5mm
Batch nr	10734
Production date	18/09/2019
Quantity	8,000 NR
Customer	Digital Dental Solutions GmbH

Kind of alloy	Standards applied
Alloy for ceramic	ISO 9693-1:2012; ISO 22674:2016
Alloy for prosthesis	ISO 22674:2016
Alloy for welding	ISO 9333:2006
Alloy for bridges and crowns	ISO 22674:2016

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Declaration of conformity N° 1901298/3

Declares taking full liability that

1 - The above mentioned medical device fullfills the essential applicable requirements of Directive 93/42/CEE Annexe I concerning medical devices (harmonized with the legislative decree D.Lgs. 46/97) and all its subsequent amendments.

2 - The above mentioned medical device has been identified to belong to class IIa.

3 - The above mentioned medical device is suitable to be commercialized and it is merchandised as NON-STERILE.

4 - The above mentioned medical device is intended to be used in preparation of dental prostheses by professional operators (prosthodontists).

5 - MESA's quality system has been approved according to Directive 93/42/CEE Annex II, point 4 excluded, by TÜV SUD PRODUCT SERVICE GMBH, notified body n°0123, located in Ridlerstraße 65 – 80339 München - Germany, trough certificate n° G1 17 07 96204 004 expiring on 2023/01/16;

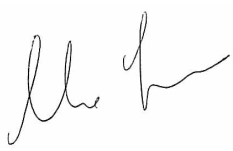
6 - MESA's quality system complies with standard UNI CEI EN ISO 13485:2016 (certificate n° Q5 096204 0005 Rev. 00 expiring on 2021/12/03); UNI CEI EN ISO 9001:2015;

7 - Other directives / standards: UNI CEI EN 1041:2013; UNI CEI EN ISO 15223-1:2012; UNI CEI EN ISO 14971:2012.

The current declaration will be stored for 15 years by the company management, in the person of Giacomo Sala.

Travagliato, 27 settembre 2019

Giacomo Sala
Managing Director



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Declaration of conformity N° 1901298/4

The undersigned company MESA di Sala Giacomo & C. S.n.c. located in via dell'Artigianato 35/37, Travagliato (BS) manufacturer of the following medical device:

Name	MAGNUM SOLARE - DISC CUT Ø98.5x15mm - Box1 - LM - MD
Destination	Alloy for ceramic
Shape / Drawing	DISC CUT Ø98.5x15mm
Batch nr	10734
Production date	18/09/2019
Quantity	12,000 NR
Customer	Digital Dental Solutions GmbH

Kind of alloy	Standards applied
Alloy for ceramic	ISO 9693-1:2012; ISO 22674:2016
Alloy for prosthesis	ISO 22674:2016
Alloy for welding	ISO 9333:2006
Alloy for bridges and crowns	ISO 22674:2016

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Declaration of conformity N° 1901298/4

Declares taking full liability that

1 - The above mentioned medical device fullfills the essential applicable requirements of Directive 93/42/CEE Annexe I concerning medical devices (harmonized with the legislative decree D.Lgs. 46/97) and all its subsequent amendments.

2 - The above mentioned medical device has been identified to belong to class IIa.

3 - The above mentioned medical device is suitable to be commercialized and it is merchandised as NON-STERILE.

4 - The above mentioned medical device is intended to be used in preparation of dental prostheses by professional operators (prosthodontists).

5 - MESA's quality system has been approved according to Directive 93/42/CEE Annex II, point 4 excluded, by TÜV SUD PRODUCT SERVICE GMBH, notified body n°0123, located in Ridlerstraße 65 – 80339 München - Germany, trough certificate n° G1 17 07 96204 004 expiring on 2023/01/16;

6 - MESA's quality system complies with standard UNI CEI EN ISO 13485:2016 (certificate n° Q5 096204 0005 Rev. 00 expiring on 2021/12/03); UNI CEI EN ISO 9001:2015;

7 - Other directives / standards: UNI CEI EN 1041:2013; UNI CEI EN ISO 15223-1:2012; UNI CEI EN ISO 14971:2012.

The current declaration will be stored for 15 years by the company management, in the person of Giacomo Sala.

Travagliato, 27 settembre 2019

Giacomo Sala
Managing Director