CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31555A	Revisione / *Revision*	3
Primo rilascio / *First issue date*	2019-04-30	Valido da / *Valid from*	2019-04-30
Scadenza / *Valid until*	2024-04-29	Ultima modifica / *Last change date*	2021-05-07

Certificato CE del Sistema di Garanzia della Qualità
EC Quality Assurance System Certificate

Si certifica che, sulla base dei risultati degli audit effettuati, il Sistema completo di garanzia di Qualità dell'Organizzazione/ *We certify that, on the basis of the audits carried out, the full Quality Assurance System of the Organization:*

LABORATOIRES ARION

Sede Legale e Operativa / *Registered and Operational Headquarter:*
694, Avenue du Docteur Maurice Donat - Parc Haute Technologie
06250 Mougins - Francia

è conforme ai requisiti applicabili della Direttiva 93/42/CEE e successive modifiche ed integrazioni, Allegato II compreso il pto 4, attuata in Italia con Dlgs. 46 del 1997/02/24 e successive modifiche ed integrazioni per le seguenti tipologie di Dispositivi Medici / *Is in compliance with the applicable requirements of 93/42/EEC Directive as amended, Annex II included point 4, transposed in Italy by Dlgs. 46 of 1997/02/24 as amended for the following Medical Devices:*

Protesi mammarie / *Breast implants*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Rif. analisi documentazione tecnica/ *Ref. technical documentation analysis:* del/dated 03/04/2020

Rif. analisi dossier progettazione/ *Ref. design dossier analysis:* del/dated 03/04/2020

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 08:50:39

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31555A	Revisione / *Revision*	3
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Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Tipologia / *Medical Devices:*
Protesi mammarie / *Breast implants*

Classe di rischio / *Risk class:*
III

Codice NANDO / *NANDO codes:*
MD 0204, MDS 7006 Moist heat

Marca / *Brandname:*
Monobloc®-Hydrogel-CMC

Modello / Model:

Round high profile hydrogel breast implant

Codici / Codes:

HY-HP (L, MT)

Modello / Model:

Round low profile hydrogel breast implant

Codici / Codes:

HY-LP (L, MT)

Codice NANDO / *NANDO codes:*
MD 0204, MDS 7006 Dry heat, chemical sterilization

Marca / *Brandname:*
Monobloc® - Silicone SoftOne®

Modello / Model:

Anatomical profile silicone breast implant

Codici / Codes:

GS-AN (T,MT) / GS-AX (T,MT) / GS-A2X (T,MT) / GS-A2XS (T,MT) / GS-A2XH (T,MT)

Modello / Model:

Round profile silicone breast implant

Codici / Codes:

GS-LP (L,T,MT) / GS-HP (L,T,MT) / GS-IP (L,T,MT) / GS-XP (L,T,MT) / GS-XXP (L,T,MT)

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
Via Cadriano, 23
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Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 08:51:03

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

CERTIFICATE

Reg. Numero / *Reg. Number*	MED 31555A	Revisione / *Revision*	3
Primo rilascio / *First issue date*	2019-04-30	Valido da / *Valid from*	2019-04-30
Scadenza / *Valid until*	2024-04-29	Ultima modifica / *Last change date*	2021-05-07

Allegato tecnico al Certificato/
Technical sheet enclosed to the Certificate

Identificazione dei Dispositivi Medici/ *Identification of Medical Devices:*

Low Profile (LP), High Profile (HP), Intermediate Profile (IP), Extra high Profile (XP), Ultra high Profile (XXP)

Anatomic Profile (AN), Extra-high anatomic Profile (AX), Extra-high anatomic Profile with projection Greater than AX (A2X), Extra-high anatomic Profile with lateral size greater than AX (A2XS), Extra-high anatomic Profile with height greater than AX (A2XH)

Smooth (L), Textured (T), Micro-textured (MT)

Il riesame della progettazione è coperto da uno specifico Certificato CE di Esame del Progetto (reg. n. MED 31555/D). / *Design assessment is covered by a specific EC-Design Examination Certificate (reg. nr.* MED 31555/*D)*

La lista completa dei codici, relativi ai modelli certificati, è disponibile presso Kiwa Cermet Italia./ *The complete list of the codes related to the certificated models is available at Kiwa Cermet Italia.* Il presente Certificato è soggetto al rispetto dei requisiti contrattuali di Kiwa Cermet Italia ed è valido solo per le tipologie di dispositivi sopra identificate soggette a sorveglianza/ *This Certificate is subject to Kiwa Cermet Italia regulations and it is valid only for the above mentioned Medical Devices that are subject to survey.* L'allegato tecnico è parte integrante del presente Certificato./ *The technical sheet is an integrating part of this Certificate.*

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta
all'attività di direzione e coordinamento
di Kiwa Italia Holding S.r.l.
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www.kiwacermet.it

Chief Operating Officer
Giampiero Belcredi

Digitally signed by:BELCREDI GIAMPIERO
Date:14/05/2021 08:51:24

CERMET

CE

Organismo Notificato n. 0476
Notified Body nr. 0476

Supplementary information to AR120 808344

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

Laboratoires Arion SAS
694 Avenue du Docteur Maurice Donat
Parc Haute Technologie
06250
Mougins
France

Date: 15 May 2024

Changes Approved:

Date	Reference Number	Action
15 May 2024	30162447	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Monobloc®- Silicone Softone® Smooth (Round) Breast Implants, Monobloc®- Silicone Softone® Microtextured (Round) Breast Implants, and Monobloc®- Silicone Softone® Microtextured (Anatomical) Breast Implants.

Inspiring trust for a more resilient world.

15 May 2024

Laboratoires Arion SAS
694 Avenue du Docteur Maurice Donat
Parc Haute Technologie
06250
Mougins
France

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
MED 31555A	AR120 808344	93/42/EEC Annex II excluding Section 4	30162447	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Monobloc®- Silicone Softone® Smooth (Round) Breast Implants, Monobloc®- Silicone Softone® Microtextured (Round) Breast Implants, and Monobloc®- Silicone Softone® Microtextured (Anatomical) Breast Implants.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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

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