CE
0425

ICIM

Approvazione del Sistema Completo di Garanzia di Qualità
Full quality assurance system approval

Certificato N.
Certificate No. **0425-MED-003241-01**

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

ORGANISMO NOTIFICATO / *NOTIFIED BODY*

ICIM S.p.A. - Identification number: 0425
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - ITALY

VISTO L'ESITO DELLE VERIFICHE CONDOTTE IN CONFORMITÀ ALL'ALLEGATO II ESCLUSO (4) DELLA DIRETTIVA EUROPEA 93/42/CEE DICHIARA CHE IL SISTEMA COMPLETO DI GARANZIA DELLA QUALITÀ ATTUATO DA:
ON THE BASIS OF THE ASSESSMENT PERFORMED ACCORDING TO ANNEX II EXCLUDING (4) OF EC DIRECTIVE 93/42/CEE DECLARES THAT THE FULL QUALITY ASSURANCE SYSTEM ENFORCED BY:

MAGNOLIA SRL

Sede Legale
Via G. Natta, 6/a - 43122 Parma (PR) - Italia
Sede Operativa
Via B. Franklin, 31/A - 43122 Parma (PR) - Italia

PER I SEGUENTI TIPI DI PRODOTTI, PROCESSI, SERVIZI
FOR THE FOLLOWING KINDS OF PRODUCTS, PROCESSES, SERVICES

Disinfettanti per dispositivi dentali.

Disinfectants for dental devices.

È CONFORME AI REQUISITI / *IS IN COMPLIANCE WITH REQUIREMENTS*

Allegato II ESCLUSO (4) della Direttiva Europea 93/42/CEE
Annex II EXCLUDING (4) of EC Directive 93/42/EEC

Per l'identificazione dei modelli di prodotto vedere l'Allegato / *For identification of the model type see Annex*

Il presente Certificato è da ritenersi valido solo se accompagnato dal relativo Allegato / *This Certificate is valid only with the relative Annex*

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
21/11/2017	**30/04/2021**	**26/05/2024**

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ICIM

Approvazione del Sistema Completo di Garanzia di Qualità
Full quality assurance system approval

ALLEGATO AL / *ANNEX TO*

Certificato N.
Certificate No. **0425-MED-003241-01**

Secondo l'allegato II, escluso (4) della Direttiva Europea 93/42/CEE (recepita con il Dlg n. 46 del 24.02.97)
According to Annex II, excluding (4) of EC Directive 93/42/CEE (as transposed into Dlg n. 46 issued on 24.02.97)

IDENTIFICAZIONE TIPOLOGIE E MODELLI
IDENTIFICATION OF THE MODEL/TYPE

Disinfettanti per dispositivi dentali cl. IIa
Disinfectants for dental devices cl. IIa

Prodotto *Product*
Puli Jet Plus 2.0
Puli Jet Pus New
Puli Jet Gentle
Puli Jet Gentle 2.0
Antischiumogeno disinfettante
Eco Jet 1 Spray
Eco Jet 1 Spray ricarica
Eco Jet 1 Tissue
Aqua Plus
Aqua Plus 2.0

Disinfettanti per dispositivi dentali cl. IIb
Disinfectants for dental devices cl. IIb

Prodotto *Product*
Fast & Steril
Fast & Steril 3 Impronte

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
21/11/2017	**30/04/2021**	**26/05/2024**

MAGNOLIA
CHEMICAL PROFESSIONALS

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**MAGNOLIA S.r.l.**
Manufacturer address and contact details	**Registered office** Via Natta, 6/A - 43122 PARMA (PR) - Italy **Operational headquarters** Via B. Franklin, 31/A - 43122 PARMA (PR) - Italy Email: info@cattani.it Phone number: +39 0521 607604
Single Registration Number (SRN) (if available)	IT-MF-000028864

Authorised Representative name (if applicable)	NA
Authorised Representative address and contact details	NA
Single Registration Number (SRN) (if available)	NA

Notified body name (if applicable)	☒ See attached schedule
Notified body number (if applicable)	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	☒ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	☒ See attached schedule
End date of extended validity/transition period	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☒ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has made by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule its substitute(s) and signed written agreement(s) is be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

  ☐

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☒ A QMS in accordance with Article 10(9) MDR is in place.
☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Magnolia S.r.l.

Parma (PR), 19/04/2024

Chief Excutive Officer

Ennio Cattani

MAGNOLIA
CHEMICAL PROFESSIONALS

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Disinfectants for dental devices: **Antischiumogeno Disinfettante** **Eco Jet 1 Spray** **Eco Jet 1 Spray Ricarica** **Salviettine Eco Jet 1 Tissue** **Aqua Plus 2.0** **Puli Jet Plus 2.0**	**0425-MED-003241-01**	**2024.05.26**	**ICIM S.p.A. - O.N. 0425**	**ICIM S.p.A. – O.N. 0425**	**31 December 2028**	**NA**

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

MAGNOLIA SRL
VIA B. FRANKLIN, 31/A - 43122 PARMA (PR) IT - Italia
2024.04.15

Notified Body Confirmation Letter
Reference: 129175

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, ICIM SPA, Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0425 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

MAGNOLIA SRL
VIA B. FRANKLIN, 31/A - 43122 PARMA (PR) IT - Italia

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the ICIM has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

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- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,
ICIM SPA
Piazza Don Enrico Mapelli, 75
2099 Sesto San Giovanni MI
Identification on NANDO CE0425

Table 1: Devices covered by this letter and for which ICIM SPA is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disinfectants for dental devices: Antischiumogeno Disinfettante Eco Jet 1 Spray Eco Jet 1 Spray Ricarica Salviettine Eco Jet 1 Tissue Aqua Plus 2.0 Puli Jet Plus 2.0	Class IIa	N/A	Certificate nr. 0425 MED 003241/01, NB 0425

Table 2: Devices covered by this letter and for which ICIM SPA is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024.04.15	129175	Initial issue

Remaining at your disposal for any clarification on the content of this letter, we take this opportunity to extend our best regards.

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Edoardo Dossena
Product Sales Manager Product Certification,
Inspections and Directives
ICIM S.p.A.

Flavia Lepore
Sales Director
ICIM S.p.A.

MAGNOLIA
CHEMICAL PROFESSIONALS

DECLARATION OF CONFORMITY

We undersigned MAGNOLIA S.r.l., with registered office addressed in Via G. Natta 6/a - 43122 Parma, and headquarters office addressed in Via B. Franklin 31/a- 43122 Parma, declare under its own responsibility that the medical devices:

Medical device	Risk class	Rule
ANTISCHIUMOGENO DISINFETTANTE	IIa	15
ECO JET 1 TISSUE	IIa	15
ECO JET 1 SPRAY	IIa	15
ECO JET 1 SPRAY RICARICA	IIa	15
PULI JET PLUS 2.0 -PULI JET GENTLE 2.0	IIa	15
AQUA PLUS - AQUA PLUS 2.0	IIa	15
PULI JET PLUS NEW - PULI JET GENTLE	IIa	15
FAST & STERIL 3	IIb	15
FAST & STERIL 3 IMPRONTE	IIb	15

according to the Directive 93/42/EEC and further amendments, Annex IX (enforced in Italy by Legislative Decree No. 46/1997 and further amendments), as amended by the Directive 2007/47/EC (enforced in Italy by Legislative Decree No. 37/10):

- are manufactured in accordance with the Quality System that meets the requirements set out in Annex II of the aforementioned Legislative Decree, as per Certificate no. 0425-MED-003241-01 issued on 30 April 2021, expiring on 26 May 2024, by the Notified Body ICIM S.p.a. n. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

Place	Date	Legal Representative
Parma	12.07.2022	Ing. Ennio Cattani

Magnolia s.r.l. Via Natta, 6/A 43122 Parma – Italy T +39 0521 607604 - info.magnolia@cattani.it - F +39 0521 399967
C.F. e P.I. 02233510342 - Capitale Sociale EUR 80.000 I.V. - R.E.A. PR221411
Registro Imprese Parma n. 02233510342