CE
0425

ICIM

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

Certificato N.
Certificate No. **0425-MED-003133-01**

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:

CATTANI SPA
Sede Legale e Operativa
Via Natta, 6/A 43122 Parma PR
Italia

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

Aspiratori per odontoiatria "ASPI JET". Compressori a secco
Dental aspirators "ASPI JET". Oil less compressors

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*
13/07/2017	**25/05/2021**	**26/05/2024**

0601CM_01_IT

CE
0425

ICIM

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

ALLEGATO AL / *ANNEX TO*

Certificato N.
Certificate No. **0425-MED-003133-01**

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

PRODOTTO/*PRODUCT*	DENOMINAZIONE/*NAME*
Aspiratori per odontoiatria, Classe IIa *Dental aspirators, Class.IIa*	ASPI JET 6γ ASPI JET 7γ ASPI JET 8γ ASPI JET 9γ
Compressori a secco, Classe IIa *Oil less compressors, Class IIa*	AC100 AC200 AC300 AC400 AC600

Gaetano Trizio
Rappresentante Direzione / Management Representative

ICIM S.p.A.

PRIMA EMISSIONE *FIRST ISSUE*	EMISSIONE CORRENTE *CURRENT ISSUE*	DATA DI SCADENZA *EXPIRING DATE*
13/07/2017	**25/05/2021**	**26/05/2024**

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CATTANI S.P.A.
VIA NATTA, 6/A - 43122 PARMA (PR) IT – Italia
2024.04.15

Notified Body Confirmation Letter
Reference: 129167

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:

CATTANI S.P.A.
VIA NATTA, 6/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

ICIM SpA Società soggetta all'attività di direzione e coordinamento di ICIM GROUP Srl
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) - Tel. +39 02 725341 Fax +39 02 72002098 - www.icim.it - info@icim.it
Capitale sociale € 260.000,00 int. versato ed esistente - C.F./P.IVA e Iscriz. Reg. Imprese di Milano n. 12908230159 – R.E.A. n. 1596292

- 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
Dental aspirators "Aspijet"	Class IIa	N/A	Certificate nr. 0425-MED-003133-01, NB 0425
Oil Less Compressors	Class IIa	N/A	Certificate nr. 0425-MED-003133-01, NB 0425
Dental asprirations tips	Class IIa	N/A	Certificate nr. 0425-MED-003141-01, NB 0425

Table 2: Devices covered by this letter and for which ICIM SPA is NOT 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	129167	Initial issue

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

1438CM_QT_EN

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

Flavia Lepore
Sales Director
ICIM S.p.A.

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	**CATTANI S.p.A.**
Manufacturer address and contact details	**Registered office - Operational headquarters** Via Natta, 6/A 43122 PARMA (PR) Italy Email: info@cattani.it Phone number: +39 0521 607604
Single Registration Number (SRN) (if available)	IT-MF-000028863

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.

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:

CATTANI S.p.A.

Parma (PR), 19/04/2024

Chief Excutive Officer

Ennio Cattani

CATTANI
AIR TECHNOLOGY

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)
Dental aspirator "ASPI JET"	**0425-MED-003133-01**	**2024.05.26**	**ICIM S.p.A. - O.N. 0425**	**ICIM S.p.A. – O.N. 0425**	**31 December 2028**	**NA**
Oil less compressors	**0425-MED-003133-01**	**2024.05.26**	**ICIM S.p.A. - O.N. 0425**	**ICIM S.p.A. – O.N. 0425**	**31 December 2028**	**NA**
Dental aspirations tips	**0425-MED-003141-01**	**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)

DICHIARAZIONE DI CONFORMITÀ CE

La Societ CATTANI S.P.A., con sede legale e operativa Via Natta 6/a - Parma, dichiara, sotto la propria totale responsabilit , che gli aspiratori per studi dentistici denominati:

1. Tipo Aspi-Jet 6/7/8/9/γ

classe di rischio IIa, in accordo alla regola 11 dell'allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepito in Italia con Decreto Legislativo 24 febbraio 1997, n. 46, e ss.mm.ii.)

- conforme ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'Azienda;
- è fabbricato in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato II escluso punto 4 del Decreto Legislativo suindicato, come da Certificato n. 0425- MED-003133-01 rilasciato in data 25.05.2021 con scadenza 26.05.2024 da ICIM – Organismo Notificato n. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

conforme alla direttiva 2011/65/UE del Parlamento europeo e del Consiglio dell'8 giugno 2011, sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.

EF-OVERENSSTEMMELSESERKLÆRING

CATTANI S.P.A., med registreret kontor og operationelt hovedkvarter i Via Natta 6/a - Parma, erklærer, under deres fulde ansvar, at sugeenhederne for tandlægeoperationer navngivet:

1. Type Aspi-Jet 6/7/8/9/γ

risikoklasse IIa, i henhold til regel 11 i bilag 9 til direktiv 93/42/EØF som ændret og integreret (implementeret i Italien med lovdekret nr. 46 24. februar 1997 som ændret og integreret)

- overholder de væsentlige krav og med bestemmelserne i direktiv 93/42/EØF som ændret og integreret i henhold til teknisk dossier indgivet p virksomhedens kontorer;
- er fremstillet i overensstemmelse med et kvalitetssystem, der overholder kravene i bilag II, ekskl. punkt pr. certifikat nr. 0425-MED-003133-01 udstedt den 25.05.2021, udløber den 26.05.2024, af det bemyndigede organ ICIM S.p.a. ingen. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

overholder Europa-Parlamentets og R dets direktiv 2011/65/EU af 8. juni 2011 om begrænsninger af brugen af farlige stoffer i elektrisk og elektronisk udstyr.

EÜ VASTAVUSDEKLARATSIOON

CATTANI S.P.A., mille registrij rgne asukoht ja peakorter asub aadressil Via Natta 6/a - Parma, kinnitab oma t ielikul vastutusel, et hambakirurgia jaoks m eldud imis steemid nimega:

1. Tüüp Aspi-Jet 6/7/8/9/γ,

riskiklass IIa, vastavalt muudetud ja integreeritud direktiivi 93/42/EM 9. lisa reeglile 11 (rakendatud Itaalias seadusandliku dekreediga nr 46, 24. veebruar 1997, muudetud ja integreeritud kujul),

- vastab n uetele ja direktiivi 93/42/EM muudetud ja integreeritud s tetele vastavalt ettev tte kontoris olevale tehnilisele toimikule;
- on toodetud vastavalt kvaliteedis steemile, mis vastab II lisas s testatud n uetele, v ljа arvatud punkt vastavalt serdile nr 0425-MED-003133-01, mis on v ljа antud 25.05.2021 ja aegub 26.05.2024, v ljastanud teavitatud asutus ICIM S.p.a. no. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI);

vastab Euroopa Parlamendi ja N ukogu 8. juuni 2011 direktiivile 2011/65/EL ohtlike ainete kasutamise piirangute kohta elektri- ja elektroonikaseadmetes.

EC DECLARATION OF CONFORMITY

CATTANI S.P.A., with registered office and operational headquarters in Via Natta 6/a - Parma, declare, under their full responsibility, that the suction units for dental surgeries named:

1. Type Aspi-Jet 6/7/8/9/γ

risk class IIa, pursuant to regulation 11 of annex 9 of Directive 93/42/EEC as amended and integrated (implemented in Italy with Legislative Decree no. 46 24 February 1997 as amended and integrated)

- complies with the essential requirements and with the provisions of Directive 93/42/EEC as amended and integrated as per Technical Dossier filed in the Company's offices;
- is manufactured in accordance with a Quality System that complies with the requirements set forth in Annex II excluding point as per certificate no. 0425-MED-003133-01 issued on 25.05.2021, expiring on 26.05.2024, by the Notified Body ICIM S.p.a. no. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

complies with directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, on restrictions on the use of hazardous substances in electrical and electronic equipment.

DEARBHŮ COMHRÉIREACHTA CE

Dearbha onn CATTANI S.P.A., ag a bhfuil oifig chl raithe agus ceanncheathr oibr ocht il ag Via Natta 6/a - Parma, faoina fhreagracht ioml n, maidir leis na haonaid s ch in le haghaidh lialanna fiacl ra darbh ainm:

1. Cineál Aspi-Jet 6/7/8/9/γ

aicme riosca IIa, de bhun rialachán 11 d'iarscríbhinn 9 de Threoir 93/42/CEE arna leas agus arna chomhth th (arna cur chun feidhme san lod il le Foraithne Reachtach uimh. 46 an 24 Feabhra 1997 arna leas agus arna comhth th)

- go gcomhl onann siad na ceanglais fh or-riachtanacha agus for lacha Threoir 93/42/CEE arna leas agus arna comhth th mar a shonra tear sa Sainchomhad Teicni il a chomhda tear in oifig na Cuideachta;
- go monara tear iad i gcomhr ir le C ras C il ochta a chomhl onann na ceanglais a leagtar amach in larscr bhinn II c is moite den phointe de r ir theastas uimh. 0425-MED-003133-01 arna eisi int an 25.05.2021, a rachaidh in ag an 26.05.2024, ag an gcomhlacht faoina dtugtar f gra ICIM S.p.a. uimh. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

go gcomhl onann siad Treoir 2011/65/AE Pharlaimint na hEorpa agus n gComhairle an 8 Meitheamh 2011 maidir le srianta ar shubstaint guaiseacha a s id i dtrealamh leictreach agus leictreonach

EK MEGFELELŐSÉGI NYILATKOZAT

A CATTANI S.P.A., sz khelye s operat v k zpontja: Via Natta 6/a - Parma, teljes felelőss ggel kijelenti, hogy a megnevezett, fogorvosi rendelőkbe sz nt sz v egys gek:

1. Típus: Aspi-Jet 6/7/8/9/γ

IIa. kock zati oszt ly , a m dos tott s integr lt 93/42/EGK ir nyelv (Olaszorsz gban a m dos tott s integr lt 1997. febru r 24-i 46. sz m t rv nyerejű rendelettel v grehajtott) 9. mell klet nek 11. szab lya szerint

- megfelel az alapvető k vetelm nyeknek s a 93/42/EGK ir nyelv m dos tott s a V llalat irod iban elhelyezett műszaki dokument ci ban foglalt rendelkez seknek;
- az ICIM S.p.a. n. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI) ltal 2021. m jus 25- n kiadott, 2024. m jus 26- n lej r , 0425-MED-003133-01 tan s tv nysz m , a II. mell kletben meghat rozott k vetelm nyeknek megfelelő minős gbiztos t si rendszerrel sszhangban k sz l.

megfelel a vesz lyes anyagok elektromos s elektronikus berendez sekben val alkalmaz s nak korl toz s r l sz l , 2011. j nius 8-i 2011/65/EU eur pai parlamenti s tan csi ir nyelvnek.

EB ATITIKTIES DEKLARACIJA

CATTANI S.P.A., kurios registruota buveinė ir veiklos adresas yra Via Natta 6/a – Parma, prisiimdama visą atsakomybę pareiškia, kad šie stomatologinių kabinetų siurbimo įtaisai:

1. Tipas „Aspi-Jet" 6 / 7 / 8 / 9 / γ

IIa rizikos klasė pagal pakeistos ir integruotos Direktyvos 93/42/EEB 9 priedo 11 taisyklę (Italijoje įgyvendinta 1997 m. vasario 24 d. įstatyminiu dekretu Nr. 46 su pakeitimais ir papildymais)

- atitinka esminius Direktyvos 93/42/EEB su pakeitimais ir papildymais reikalavimus ir nuostatas, kaip nurodyta Bendrovės biure pateiktame techniniame dokumentų rinkinyje;

- gaminami pagal kokybės sistemą, atitinkančią II priede nustatytus reikalavimus, išskyrus II priedo punktą, kaip nurodyta notifikuotosios įstaigos ICIM S.p.a. Nr. 0425, Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI) sertifikate Nr. 0425-MED-003133-01, išduotame 2021-05-25, kurio galiojimas baigiasi 2024-05-26.

  atitinka 2011 m. birželio 8 d. Europos Parlamento ir Tarybos direktyvą 2011/65/ES dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo.

ES ATBILSTĪ BAS DEKLARĀCIJA

CATTANI S.P.A., kura juridiskā un faktiskā adrese ir Via Natta 6/a - Parma, ar pilnu atbildību paziņo, ka nosūces ierīces, kas paredzētas zobārstniecības operācijām, proti:

1. Type Aspi-Jet 6/7/8/9/γ,

riska klase IIa, saskaņā ar grozītās un integrētās Direktīvas 93/42/EEK (īstenota Itālijas tiesību aktos ar 1997. gada 24. februāra grozīto un integrēto Likumdošanas dekrētu Nr. 46) 9. pielikuma 11. noteikumu

- atbilst būtiskajām prasībām un grozītās un integrētās Direktīvas 93/42/EEK prasībām saskaņā ar tehnisko dokumentāciju, kas tiek glabāta uzņēmuma birojos;
- ir ražotas saskaņā ar kvalitātes sistēmu, kura atbilst II pielikumā noteiktajām prasībām, izņemot punktu atbilstoši sertifikātam Nr. 0425-MED-003133-01, kurš izsniegts 25.05.2021. un ir derīgs līdz 26.05.2024. un kuru izsniegusi paziņotā struktūra ICIM S.p.a., Nr. 0425, Piazza Don Enrico Mapelli, 75–20099 Sesto San Giovanni (MI);

  atbilst Eiropas Parlamenta un Padomes 2011. gada 8. jūnija Direktīvai 2011/65/ES par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās.

DIKJARAZZJONI TA' KONFORMITÀ TAL-UE

CATTANI S.P.A., b'uffiċċju rreġistrat u kwartieri ġenerali tal-operazzjoni f'Via Natta 6/a - Parma, jiddikjaraw, taħt ir-responsabbilt sħiħa tagħhom, li l-unitajiet għall-ġbid bl-arja għal kirurġiji dentali bl-isem ta':

1. Tip Aspi-Jet 6/7/8/9/γ

klassi tar-riskju IIa, b'konformità mar-regolament 11 ta' anness 9 tad-Direttiva 93/42/KEE kif emendata u integrata (implimentata fl-Italja permezz tad-Digriet Leġislattiv nru 46 tal-24 Frar 1997, kif emendat u integrat)

- jikkonforma mar-rekwiżiti essenzjali u mad-dispożizzjonijiet tad-Direttiva 93/42/KEE kif emendata u integrata skont id-Dossier Tekniku mdaħħal fl-uffiċċji tal-Kumpanija;
- huwa mmanifatturat skont Sistema ta' Kwalità li tikkonforma mar-rekwiżiti stabbiliti fl-Anness II, minbarra l-punt skont iċ-ċertifikat nru 0425-MED-003133-01 maħruġ fil-25/05/2021, u li jiskadi fis-26/05/2024, mill-Korp Notifikat ICIM S.p.a. no. 0425, Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

  jikkonforma mad-direttiva 2011/65/UE tal-Parlament Ewropew u tal-Kunsill tat-8 ta' Ġunju 2011, dwar ir-restrizzjoni tal-użu ta' sustanzi perikolużi fit-tagħmir elettriku u elettroniku.

CE-KONFORMITÄTSERKLÄRUNG

Die Gesellschaft CATTANI S.P.A., mit Gesch ftssitz und Betriebsst tte in Via Natta 6/a - Parma, erkl rt unter eigener Verantwortung, dass die genannten Absauganlagen f r Zahnarztpraxen:

1. Typ Aspi-Jet 6/7/8/9/γ

Risikoklasse IIa, in bereinstimmung mit Regel 11 des Anhangs IX der Richtlinie 93/42/EWG in der geltenden Fassung (umgesetzt in Italien durch das gesetzesvertretende Dekret Nr. 46 vom 24. Februar 1997 in der geltenden Fassung)

- - mit den grundlegenden Anforderungen und Bestimmungen der Richtlinie 93/42/EWG in der geltenden Fassung gem ß den beim Unternehmen archivierten Technischen Unterlagen konform ist;
- - in bereinstimmung mit dem Qualit tssystem entsprechend den Anforderungen von Anhang II hergestellt wurde, ausgenommen Punkt 4 des oben genannten GvD, entsprechend der Bescheinigung Nr. MED-003133-01, ausgestellt am 25.05.2021 von der benannten Stelle Nr. 0425, Piazza Don Enrico Mapelli 75 - 20099 Sesto San Giovanni (MI) und g ltig bis zum 26.05.2024;

  konform ist mit der Richtlinie 2011/65/EU des Europ ischen Parlaments und des Rates vom 8. Juni 2011 ber die Beschr nkung der Verwendung bestimmter Gefahrenstoffe in Elektro- und Elektronikger ten.

DECLARACIÓN DE CONFORMIDAD CE

La Empresa CATTANI S.P.A., domicilio social y operativo Via Natta 6/a - Parma, declara, bajo su total responsabilidad, que los aspiradores para cl nicas dentales denominados:

1. Tipo Aspi-Jet 6/7/8/9/γ

clase de riesgo IIa, de acuerdo con la regla 11 del anexo IX de la Directiva 93/42/CEE y suces. modific. e integraciones (incorporado en Italia con Decreto Legislativo 24 de febrero de 1997, n.º 46, y sucesivas modific. e integraciones)

- resulta conforme a los requisitos esenciales y a las disposiciones de la Directiva 93/42/CEE y suces. modific. e integraciones tal y como consta en el Expediente T cnico archivado en la empresa;
- est fabricado de acuerdo con el Sistema de Calidad que satisface los requisitos mencionados en el Anexo II, punto 4 excluido, del Decreto Legislativo indicado anteriormente, tal y como consta en el Certificado n.º 0425-MED-003133-01 expedido con fecha 25.05.2021, con vencimiento el 26.05.2024 por ICIM – Organismo Notificado n.º 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (Mil n);

resulta conforme a la Directiva 2011/65/UE del Parlamento europeo y del Consejo de 8 de junio de 2011, sobre la restricci n del uso de determinadas sustancias peligrosas en los aparatos el ctricos y electr nicos.

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ CE

Η εταιρεία CATTANI S.P.A., με νόμιμη και λειτουργική έδρα στη Parma, 43122, [οδός] Via Natta 6/a, δηλώνει, υπό την πλήρη ευθύνη της, ότι οι οδοντιατρικοί αναρροφητήρες με την ονομασία:

1. Τύπος Aspi-Jet 6/7/8/9/γ

Κατηγορία κινδύνου IIa, σύμφωνα με τον κανόνα 11 του παραρτήματος IX της Οδηγίας 93/42/ΕΟΚ και των μεταγενέστερων τροποποιήσεων και συμπληρωμάτων. (εφαρμόζεται στην Ιταλία με το νομοθετικό διάταγμα αριθ. 46 της 24ης Φεβρουαρίου 1997, όπως τροποποιήθηκε).

- Συμμορφώνονται με τις βασικές απαιτήσεις και διατάξεις της Οδηγίας 93/42/ΕΟΚ και των μεταγενέστερων τροποποιήσεων και συμπληρωμάτων, σύμφωνα με τον Τεχνικό Φάκελο που είναι αρχειοθετημένος στην Εταιρεία.
- Κατασκευάζονται σύμφωνα με το Σύστημα Ποιότητας που πληροί τις απαιτήσεις του Παραρτήματος II, εξαιρουμένου του σημείου 4 του προαναφερθέντος Νομοθετικού Διατάγματος, σύμφωνα με το Πιστοποιητικό αρ. 0425- MED-003133-01 που εκδόθηκε στις 25.05.2021 με λήξη στις 26.05.2024, από τον Κοινοποιημένο Οργανισμό αριθ. 0425 - ICIM S.p.a., Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

Συμμορφώνεται με την οδηγία 2011/65/ΕΕ του Ευρωπαϊκού Κοινοβουλίου και του Συμβουλίου, της 8ης Ιουνίου 2011, για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό.

EZ IZJAVA O SUKLADNOSTI

Tvrtka CATTANI S.P.A., s registriranim i poslovnim sjedištem u ul. Natta 6/a - Parma, daje izjavu, pod punom vlastitom odgovornošću, da su aspiratori za stomatološke ordinacije pod nazivom:

1. Tip Aspi-Jet 6/7/8/9/γ

razred rizika IIa, u skladu s pravilom 11. priloga IX Direktive 93/42/EEZ i naknadnim izmjenama i dopunama (koja je usvojena u Italiji Zakonskom uredbom od 24. veljače 1997.g., br. 46, i naknadnim izmjenama i dopunama)

- u skladu s osnovnim zahtjevima i odredbama Direktive 93/42/EEZ i naknadnim izmjenama i dopunama, kako proizilazi iz tehničkih brošura koje se nalaze u arhivu tvrtke;
- proizvedeni u skladu sa Sustavom kvalitete koji ispunjava zahtjeve iz Priloga II izuzev točke 4. prethodno navedene zakonske uredbe, prema Certifikatu br. 0425- MED-003133-01 izdanom 25.05.2021., a koji traje do 26.05.2024., sa strane ICIM – prijavljeno tijelo br. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);
- sukladni Direktivi 2011/65/EU Europskog parlamenta i vijeća od 8. lipnja 2011.g. o ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi.

EG-CONFORMITEITSVERKLARING

Het Bedrijf CATTANI S.P.A., met juridische en operationele zetel in Via Natta 6/a - Parma, verklaart, onder haar uitsluitende verantwoordelijkheid, dat de zuigers voor tandartspraktijken genaamd:

1. Type Aspi-Jet 6/7/8/9/γ

risicoklasse IIa, volgens de norm 11 van de bijlage IX van de Richtlijn 93/42/CEE en latere wijzigingen (geïmplementeerd in Italië met wetsdecreet 24 februari 1997, n. 46, en latere wijzigingen)

- voldoet aan de essentiële eisen en de bepalingen van Richtlijn 93/42/EEG en latere wijzigingen, volgens het technisch dossier dat bij het bedrijf gearchiveerd is;
- vervaardigd is in overeenstemming met het kwaliteitssysteem dat voldoet aan de eisen van bijlage II met uitzondering van punt 4 van het bovengenoemde wetsbesluit, volgens certificaat nr. 0425- MED-003133-01 afgegeven op 25.05.2021, geldig tot 26.05.2024, door ICIM - Aangemelde instantie n. 0425 - Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI).

voldoet aan Richtlijn 2011/65/EU van het Europees Parlement en de Raad van 8 juni 2011 betreffende de beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.

DEKLARACJA ZGODNOŚCI WE

Spółka CATTANI S.P.A. z siedzibą i miejscem wykonywania działalności na Via Natta 6/a – Parma oświadcza na własną całkowitą odpowiedzialność, że ssaki do gabinet w stomatologicznych pod nazwą:

1 Typ Aspi-Jet 6/7/8/9/γ

klasa zagrożenia IIa, zgodnie z zasadą 11 załącznika IX Dyrektywy 93/42/EWG z p źn. zm. i uzup. (transponowanej we Włoszech Dekretem z mocą ustawy nr 46 z dn. 24 lutego 1997 r., z p źn. zm. i uzup.)

- spełniają zasadnicze wymagania i postanowienia Dyrektywy 93/42/EWG z p źn. zm. i uzup., zgodnie z dokumentacją techniczną złożoną w przedsiębiorstwie;
- są produkowane zgodnie z systemem jakości spełniającym wymagania Załącznika II, z wyjątkiem punktu 4, wyżej wymienionego Dekretu z mocą ustawy, zgodnie z Certyfikatem nr 0425- MED-003133-01 wydanym dn. 25.05.2021 r. z datą ważności 26.05.2024 r. przez ICIM – jednostkę notyfikowaną nr 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

są zgodne z Dyrektywą Parlamentu Europejskiego i Rady 2011/65/UE z dn. 8 czerwca 2011 r. w sprawie ograniczenia stosowania niekt rych substancji niebezpiecznych w sprzęcie elektrycznym i elektronicznym.

DECLARAÇÃO DE CONFORMIDADE CE

A Empresa CATTANI S.P.A., com sede registada e operativa situada em Via Natta 6/a - Parma, It lia, declara, sob a sua plena responsabilidade, que os aspiradores destinados a cl nicas dent rias, denominados:

1. Tipo Aspi-Jet 6/7/8/9/γ

classe de risco IIa, em conformidade com a regra 11 do Anexo IX da Diretiva 93/42/CEE e subsequentes altera es e suplementos (implementado em It lia pelo Decreto Legislativo n.º 46 de 24 de Fevereiro de 1997, subsequentes altera es e suplementos)

- cumpre os requisitos essenciais e disposi es da Diretiva 93/42/CEE e subsequentes altera es e suplementos, de acordo com o Relat rio T cnico arquivado junto da Empresa;
- fabricado em conformidade com o Sistema de Qualidade que satisfaz os requisitos do Anexo II exclu do ponto 4 do Decreto Legislativo acima referido, conforme Certificado n.º 0425- MED-003133-01 emitido em data 25.05.2021 com validade a 26.05.2024 por ICIM – Organismo Notificado n.º 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

cumpre a Diretiva 2011/65/UE do Parlamento Europeu e do Conselho, de 8 de Junho de 2011, relativa restri o do uso de determinadas subst ncias perigosas em equipamentos el tricos e eletr nicos.

DECLARAȚIE DE CONFORMITATE CE

Societatea CATTANI S.P.A., cu sediul legal și operațional în Via Natta 6/a - Parma, declară pe proprie răspundere că aspiratoarele pentru cabinete stomatologice denumite:

1. Tip Aspi-Jet 6/7/8/9/γ

clasă de risc IIa, în conformitate cu regula 11 din anexa IX la Directiva 93/42/CEE, cu modificările și completările ulterioare (implementată în Italia prin Hotărârea Guvernului nr. 46 din 24 februarie 1997, cu modificările și completările ulterioare),

sunt conforme cu cerințele esențiale și prevederile Directivei 93/42/CEE, cu modificările și completările ulterioare, conform Dosarului tehnic aflat în arhiva Companiei;

sunt fabricate în conformitate cu Sistemul de Calitate care îndeplinește cerințele din Anexa II, cu excepția punctului 4, la Hotărârea Guvernului menționată anterior, conform Certificatului nr. 0425- MED-003133-01 eliberat pe data de 25.05.2021, valabil până pe 26.05.2024, de către ICIM – Organism Notificat nr. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

sunt conforme cu directiva 2011/65/UE a Parlamentului European și a Consiliului din 8 iunie 2011, privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice.

ES PROHLÁŠENÍ O SHODĚ

Společnost CATTANI S.P.A. se s dlem a provozem na Via Natta 6/a – Parma prohlašuje na vlastní zodpovědnost, že odsávače určen pro zubn ambulance s n zvem:

1. Typ Aspi-Jet 6/7/8/9/γ

tř da rizika IIa v souladu s nař zen m 11 podle př lohy IX k Směrnici 93/42/EHS ve zněn pozdějších změn a doplněn (v It lii implementovanou Legislativn m dekretem č. 46 z 24. nora 1997 ve zněn pozdějších změn a doplněn)

- jsou ve shodě se základními požadavky a s ustanoven mi Směrnice 93/42/EHS ve zněn pozdějších změn a doplněn tak, jak vypl v z technické dokumentace uložené ve společnosti,
- se vyr běj v souladu se Syst mem kvality, kter splňuje požadavky ustanoven v Př loze II (s vyj mkou bodu 4) k uveden mu Legislativn mu dekretu tak, jak vypl v z Osvědčen č. 0425- MED-003133-01 vydan ho dne 25.05.2021 s platnost do 26.05.2024 společnost ICIM – notifikovanou organizac č. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

  jsou shodn se Směrnic 2011/65/EU Evropsk ho parlamentu a Rady z 8. června 2011 o omezení používání určit ch nebezpečn ch l tek v elektrick ch a elektronick ch zař zen ch.

ES VYHLÁSENIE O ZHODE

Spoločnosť CATTANI S.P.A. so sídlom a prevádzkou na Via Natta 6/a – Parma vyhlasuje na vlastnú zodpovednosť, že odsávače určené pre zubné ambulancie s názvom:

1. Typ Aspi-Jet 6/7/8/9/γ

trieda rizika IIa v s lade s pravidlom 11 podľa pr lohy IX k Smernici 93/42/EHS v znen neskorších zmien a doplnen (v Taliansku implementovanej Legislat vnym dekr tom č. 46 z 24. febru ra 1997 v znení neskorších zmien a doplnen)

- sú zhodné so základnými požiadavkami a ustanoveniami Smernice 93/42/EHS v znení neskorších zmien a doplnen tak, ako vypl va z technickej dokumentácie uloženej v spoločnosti,
- sa vyr baj v s lade so Syst mom kvality, ktor spĺňa požiadavky ustanovené v Prílohe II (s výnimkou bodu 4) uvedeného Legislat vneho dekr tu tak, ako vypl va z Osvedčenia č. 0425- MED-003133-01 vydan ho dňa 25.05.2021 s platnosťou do 26.05.2024 spoločnosťou ICIM – notifikovanou organiz ciou č. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

  s zhodn so Smernicou 2011/65/E Eur pskeho parlamentu a Rady z 8. j na 2011 o obmedzení používania určit ch nebezpečn ch l tok v elektrick ch a elektronick ch zariadeniach.

ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ НА ЕО

Фирма „КАТАНИ" АД (CATTANI S.P.A.) със седалище и адрес на управление на ул. „Ната" № 6/а – Парма декларира изцяло на собствена отговорност, че аспираторите за стоматологични кабинети със следното наименование:

1. Тип Aspi-Jet 6/7/8/9/γ

клас на риск IIa, съгласно правило 11 на приложение IX на Директива 93/42/ЕИО и следващите изменения и допълнения (възприета в Италия със Законодателен декрет № 46 от 24 февруари 1997 г. и последващите изменения и допълнения)

- отговаря на съществените изисквания и на разпоредбите на Директива 93/42/ЕИО и последващите изменения и допълнения съгласно техническото досие, съхранявано в архива на фирмата;

- е произведено според Системата за качество, която отговаря на изискванията, описани в Приложение II, с изключение на точка 4 на горепосочения Законодателен декрет, съгласно Сертификат № 0425-MED-003133-01, издаден на 25.05.2021 и с валидност до 26.05.2024 от ICIM – Нотифициран орган № 0425 – пл. „Дон Енрико Мапели" №75 – 20099 Сесто Сан Джовани (пров. Милано);

  отговаря на изискванията на директива 2011/65/ЕС на Европейския парламент и на Съвета от 8 юни 2011 г. относно ограничение за употребата на определени опасни вещества в електрическото и електронното оборудване.

EU-VAATIMUSTENMUKAISUUSVAKUUTUS

Yhtiö CATTANI S.P.A., pääkonttori ja toimipaikka Via Natta 6/a - Parma - Italia, vakuuttaa yksinomaisella vastuullaan, että hammashoitoon tarkoitetut imurit tuotenimeltä:

1. Tyyppi Aspi-Jet 6/7/8/9/γ

riskiluokka IIa direktiivin 93/42/ETY ja sen muutosten (saatettu osaksi Italian lainsäädäntöä lakiasetuksella nro 46, 24. helmikuuta 1997, ja sen muutoksilla) liitteen IX säännön 11 mukaan

- on direktiivin 93/42/ETY ja sen muutosten olennaisten vaatimusten ja säännösten mukainen, kuten ilmenee yhtiön tiloissa säilytetystä teknisestä eritelmästä
- on valmistettu soveltamalla laatujärjestelmää, joka on yllä mainitun lakiasetuksen liitteen II vaatimusten mukainen (kohtaa 4 lukuun ottamatta), mikä ilmenee ICIM-yrityksen – ilmoitettu laitos nro 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI) – Italia, 25.05.2021 myöntämästä sertifikaatista nro 0425- MED-003133-01, jonka voimassaolon päättymispäivä on 26.05.2024.

  on Euroopan parlamentin ja neuvoston direktiivin 2011/65/EU, annettu 8 päivänä kesäkuuta 2011, tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa, mukainen.

DÉCLARATION DE CONFORMITÉ CE

L'entreprise CATTANI S.P.A., dont le si ge social et op rationnel se trouve Via Natta 6/a, Parme (Italie) d clare, sous son enti re responsabilit , que les aspirateurs pour cabinets dentaires appel s :

1. Type Aspi-Jet 6/7/8/9/γ

classe de risque IIa, conform ment la r gle 11 de l'annexe IX de la directive 93/42/CEE et ses modifications ult rieures (transpos e en Italie par le d cret l gislatif n° 46 du 24 f vrier 1997 et ses modifications ult rieures)

- est conforme aux exigences essentielles et aux dispositions de la directive 93/42/CEE et ses modifications ult rieures, selon le Dossier technique archivé dans l'entreprise ;
- est fabriqu conform ment au syst me qualit qui r pond aux exigences de l'annexe II, l'exception du point 4 du d cret l gislatif susmentionn , conform ment au certificat n° 0425- MED-003133-01 d livr le 25.05.2021 arrivant ch ance le 26.05.2024 par ICIM – Organisme notifi n° 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (Milan, Italie) ;

  est conforme la directive 2011/65/UE du Parlement europ en et du Conseil du 8 juin 2011 relative la limitation de l'utilisation de certaines substances dangereuses dans les quipements lectriques et lectroniques.

EG IZJAVA O SKLADNOSTI

Družba CATTANI D.O.O., s glavnim sedežem in operativnim sedežem na ulici Natta 6/a - Parma, pod svojo izključno odgovornostjo potrjuje, da so navedeni zobni aspiratorji:

1. Tip Aspi-Jet 6/7/8/9/γ

Razred tveganja IIa, v skladu s pravilom 11 Priloge IX Direktive Sveta 93/42/EGS ter nadaljnjimi spremembami in dopolnitvami (uvedena v Italiji z Zakonsko uredbo z dne 24. februarja 1997, št. 46 ter nadaljnjimi spremembami in dopolnitvami.)

- so v skladu z bistvenimi zahtevami in določbami Direktive 93/42/EGS ter nadaljnjimi spremembami in dopolnitvami, v skladu s tehničnimi datotekami, ki so arhivirane v podjetju;
- so izdelani v skladu s Sistemom kakovosti, ki izpolnjuje zahteve Priloge II, razen točke 4 zgoraj navedene Zakonske uredbe, v skladu s certifikatom št. 0425- MED-003133-01, ki ga je izdal priglašeni organ ICIM dne 25.05.2021 in ki zapade dne 26.05.2024, št. 0425 – Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI);

so v skladu z Direktivo 2011/65/UE Evropskega parlamenta in Sveta z dne 8. junija 2011 o omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi.

EG-FÖRSÄKRAN OM ÖVERENSSTÄMMELSE

Bolaget CATTANI S.P.A., med säte och huvudkontor p Via Natta 6/a – Parma – Italien, försäkrar p eget ansvar att sugapparaterna för tandläkarmottagningar med benämningen:

1. Typ Aspi-Jet 6/7/8/9/γ

i riskklass IIa enligt regel 11 i bilaga IX i direktiv 93/42/EEG, i dess ändrade lydelse (införlivat med italiensk lagstiftning genom lagstiftningsdekret nr 46 av den 24 februari 1997, i dess ändrade lydelse)

- är i överensstämmelse med de väsentliga kraven och bestämmelserna i direktiv 93/42/EEG, i dess ändrade lydelse, s som framg r av den tekniska dokumentation som förvaras hos företaget,
- tillverkas i enlighet med ett kvalitetsstyrningssystem som uppfyller kraven i bilaga II, med undantag för punkt 4, i ovannämnda lagstiftningsdekret, s som framg r av intyg nr 0425-MED-003133-01 utfärdat 2021-05-26 och giltigt t.o.m. 2024-05-06 av ICIM – Anmält organ nr 0425 – Piazza Don Enrico Mapelli 75 – IT-20099 Sesto San Giovanni (MI) – Italien,

är i överensstämmelse med Europaparlamentets och r dets direktiv 2011/65/EU av den 8 juni 2011 om begränsning av användning av vissa farliga ämnen i elektrisk och elektronisk utrustning.

UKCA 21a HARRIS BUSINESS PARK/HANBURYRD B604DJ BROMSGROVE/WORCESTERSHIRE

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Ennio Cattani 02.04.2024 16:11:43 GMT+01:00

.....Parma..... .....••••••••• ..... Ing. Ennio Cattani.

Luogo - Place - Lieu - Ort - Lugar **Data -** Date - Date - Datum - Fecha

Direttore Tecnico e persona autorizzata a custodire il fascicolo tecnico - indirizzo: via Natta 6/a Parma Italy