

Inoculating Loops

Disposable inoculating loops for collection and inoculation by streaking or puncture method. Smooth loop surfaces allows easy streaking. No rough plastic edges, flashing or burrs on the loop head. Loops do not cut or gouge the agar surface during streaking. Being both sterile and disposable eliminates the risk of cross contamination. All loops are free of any lubricants and do not contaminate any media. Color-coded sizes for easily identification.

Packages:

- 20pcs/zip-lock pack,50x20pcs/box,10x1000pcs/ctn
- 10pcs/zip-lock pack,100x10pcs/box,10x1000pcs/ctn
- 5pcs/zip-lock pack,100x5pcs/box,10x500pcs/ctn
- Individual peel pack,500pcs/box,10x500pcs/ctn

Cat No.	Description	Qty/Case(pcs)
Rigid Loops		
620601	Inoculating loops, PS, natural color,1ul	10000
620602	Inoculating loops, PS, blue color,10ul	10000
620603	Inoculating loops, PS, yellow,1ul +10ul	10000
Flexible Loops		
620604	Inoculating loops, ABS, white,1ul	10000
620605	Inoculating loops, ABS, blue,10ul	10000
620606	Inoculating loops, ABS, yellow,1ul +10ul	10000

BOEN HEALTHCARE CO., LTD.

CERTIFICATE OF ANALYSIS

Report No.: GM03-BN23

Product Name: Inoculating Loops			Specification: Flexible, 1μL				
Lot. No.: 20230501			MFG. Date: 2023-05				
EXP. Date: 2028-04			Raw Material: ABS				
Standard: Enterprise Standard							
Package: 20pcs/bag, 10000pcs/carton							
Quantity: 500000pcs			Report Date: 2023.06.10				
Item	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	1μL	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	No burr, black dot, dust, scratch, flash≤0.5mm, no oil spot, breakage. The color should be without obvious color difference.	GB/T 2828.1-2012 Normal test Level II	800pcs	1.5		1	Pass
				Ac	Re		
				21	22		
Function	The loops are no flash edge, capacity is 1μL	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	The printing should be clean and clear.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirement by out test.						

Inspector: Tom Li

Date: 2023.06.10

Checker: Leo Sun

Date: 2023.06.10



BOEN HEALTHCARE CO., LTD.

CERTIFICATE OF ANALYSIS

Report No.: GM03-BN23

Product Name: Inoculating Loops			Specification: Flexible, 10 μ L				
Lot. No.: 20230501			MFG. Date: 2023-05				
EXP. Date: 2028-04			Raw Material: ABS				
Standard: Enterprise Standard							
Package: 20pcs/bag, 10000pcs/carton							
Quantity: 500000pcs			Report Date: 2023.06.10				
Item	Technical Requirement	Inspection Level	Sample	AQL		Defect Qty	Result
Dimension	10 μ L	5pcs/lot	5pcs	0		0	Pass
				Ac	Re		
				0	1		
Appearance	No burr, black dot, dust, scratch, flash \leq 0.5mm, no oil spot, breakage. The color should be without obvious color difference.	GB/T 2828.1-2012 Normal test Level II	800pcs	1.5		0	Pass
				Ac	Re		
				21	22		
Function	The loops are no flash edge, capacity is 10 μ L	10pcs/lot	10pcs	0		0	Pass
				Ac	Re		
				0	1		
Package	The printing should be clean and clear.	1 outer box/lot	1 outer box	0		0	Pass
				Ac	Re		
				0	1		
Conclusion	The product meets all the requirement by out test.						

Inspector: Tom Li
Date: 2023.06.10

Checker: Leo Sun
Date: 2023.06.10



CERTIFICATE OF ANALYSIS

Report No.: GM03-BN23

Product Name	Serological Pipette	Specification	1ml
Lot. No.	10122123	Quantity	50000pcs
Mfg. Date	20221206	Exp. Date	20251205
Test Standard	Factory Standard	Report Date	2023.05.15
Item	Technical Requirement	Result	Conclusion
Appearance	The surface of serological pipette should be smooth, no black spot, no edges and other defects.	Comply	Qualified
	The color of the tube is transparent.	Comply	Qualified
	The graduation line should be clear, no blur.	Comply	Qualified
	The pipette is straight, no bend.	Comply	Qualified
Packaging	The Pasteur pipette should be sealed complete and there is no foreign matter in the bag.	Comply	Qualified
Sterile	The serological pipette should be sterile.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Leo Sun
Date: 2023.05.15Checker: Irene Qiao
Date: 2023.05.15

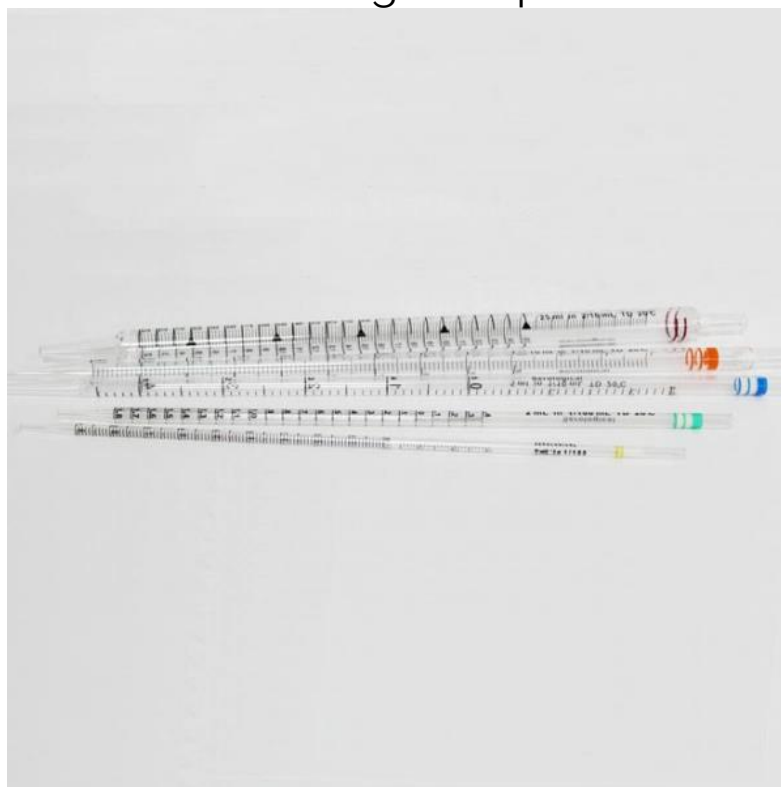
CERTIFICATE OF ANALYSIS

Report No.: GM03-BN23

Product Name	Serological Pipette	Specification	10ml
Lot. No.	11022061	Quantity	4000pcs
Mfg. Date	20220602	Exp. Date	20250601
Test Standard	Factory Standard	Report Date	2023.05.15
Item	Technical Requirement	Result	Conclusion
Appearance	The surface of serological pipette should be smooth, no black spot, no edges and other defects.	Comply	Qualified
	The color of the tube is transparent.	Comply	Qualified
	The graduation line should be clear, no blur.	Comply	Qualified
	The pipette is straight, no bend.	Comply	Qualified
Packaging	The Pasteur pipette should be sealed complete and there is no foreign matter in the bag.	Comply	Qualified
Sterile	The serological pipette should be sterile.	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Leo Sun
Date: 2023.05.15Checker: Irene Qiao
Date: 2023.05.15

Serological Pipette



Serological Pipettes

Serological Pipette, designed for quantitatively transferring and dispensing exact volumes of liquid. Manufactured from virgin polystyrene.

Accurate graduation, easy to read, color-codes by size for identification.

Available with 6 capacity of 1, 2, 5, 10, 25 and 50ml

Serological Pipettes are supplied gamma radiation, available with bulk package or in a paper/ plastic bag.

Dnase & Rnase free.

Cat No.	Description	Qty/Case
640601	Serological Pipettes, PS, 1ml	4000
640602	Serological Pipettes, PS, 2ml	3200
640603	Serological Pipettes, PS, 5ml	1800
640604	Serological Pipettes, PS, 10ml	1200
640605	Serological Pipettes, PS, 25ml	800
640606	Serological Pipettes, PS, 50ml	800

BOEN HEALTHCARE CO., LTD.

Certificate of Analysis

Report No.: GM01-BN24

Product Name	Flocked Swabs	Specification	Oral type, Nasal type
Lot. No.	20240301	Mfg. Date	20240301
Exp. Date	20270228	Order Quantity	80000pcs
Sampling Quantity	32pcs	Inspection Date	2024.03.26
Inspection Standard	Factory Standard	Report Date	2024.03.26

Item	Technical Requirement	Result	Conclusion
Appearance	The handle of the swab shall be smooth, no burrs, no flying edges.	Comply	Qualified
	The tip of the swabs shall be uniform, no foreign impurities.	Comply	Qualified
	The swab shall be without obvious color difference.	Comply	Qualified
	The tube shall be no burr, no flying edges.	Comply	Qualified
Break point	The position of the break point shall be correct.	Comply	Qualified
Sterile	The lancet shall be sterile	Comply	Qualified
Conclusion	Meet the requirement		

Inspector: Tom Li
Date: 2024.03.26

Checker: Leo Sun
Date: 2024.03.26



Flocked Swab with Tube

Flocked Swab with Tube

Flocked swab, ABS stick with nylon flocked tip, color code red in polypropylene test tube ø 12×150 mm, sterile.

Suitable for most specimen, such as from throat, vaginal, skin and wound specimens.

Package: 100pcs/bag, 1000pcs/case



Cat No.	Description	Qty/Case
612701	Flocked Swab with Tube, Nasal type, with 8cm break point. Sterile, 100pcs/bag	2000
612702	Flocked Swab with Tube, Oral type, with 3cm break point. Sterile, 100pcs/bag	2000
612703	Flocked Swab with Tube, Oral type, with 8cm break point. Sterile, 100pcs/bag	2000

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi e dispositivi medici di classe I non sterile.

Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field.

Design and manufacturing of diagnostic medical devices for laboratories of analysis and non-sterile class I medical devices.

Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana

In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date
2007-10-30

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT
2011-10-30

Data di Rinnovo
Renewal Date
2023-10-24

Data di Scadenza
Expiration Date
2026-10-29



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

SCHEDA TECNICA PRODOTTO

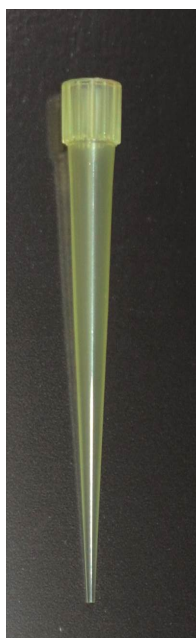
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
18.09.2023

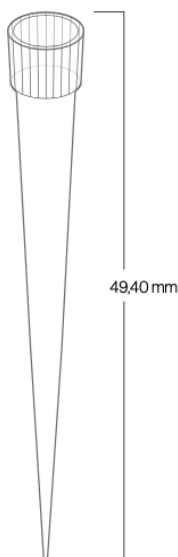


ARTICOLO: **PUNTALI PER MICROPIPETTE TIPO EPPENDORF® 5 - 200 µL**
ITEM: **TIPS FOR MICROPIPETTES EPPENDORF® TYPE 5 - 200 µL**

DESCRIZIONE / DESCRIPTION



Technical view



Puntali low retention realizzati in polipropilene medicale (PP) ad elevata purezza ed esente da Cadmio ed altri metalli pesanti. Prodotti con particolare precisione per una perfetta tenuta con le micropipette compatibili e per una ottimale direzionalità dei liquidi in fase di svuotamento. Altamente trasparenti e con ottimo grado di idrorepellenza. Autoclavabili fino a +121°C. Dispositivo Latex free. Disponibili in diversi confezionamenti:

- Non sterili in sacchetti da 1.000 pezzi
- Sterili apirogeni in confezioni da 5 pezzi o in confezione singola
- Non sterili o sterili apirogeni in rack autoclavabile con coperchio da 96 pezzi singolarmente sigillato con film trasparente per garantirne la sterilità.
- Piastrine intercambiabili (Refill) da 96 pezzi

Low retention tips made of medical polypropylene (PP) of high purity, cadmium and heavy metal free. Manufactured with particular precision, that ensures a perfect seal of the compatibles micropipettes and an optimal directionality of liquids in the emptying process. Highly transparent and with an excellent degree of waterproofness. Autoclavable up to +121°C. Latex-free device. Available with different packaging:

- *Not sterile in bags of 1,000 pieces*
- *Sterile pyrogen free in bags of 5 pieces or individually wrapped*
- *Non sterile or sterile pyrogen free in autoclavable rack with lid of 96 pieces individually sealed by transparent film to grant its sterility.*
- *Refill trays of 96 pieces*

CARATTERISTICHE PRINCIPALI		TECHNICAL FEATURES
Materiale impiegato	Polipropilene / Polypropylene	Raw material
Temperature tollerate	min -10°C max +121°C	Temperature range
Volume	5 – 200 µl	Volume
Modello	EPPENDORF® all model	Type
Compatibilità	Gilson® Pipetman P20-100-200 - Biohit® Proline & mLine – Brand® Transferpette - Socorex® Acura & Calibra – HTL® Discovery - Nichiryo® - Thermo Scientific™ Finn pipette™ and similar	Compatibility
Lunghezza totale (mm)	49,40	Total length (mm)
Peso (g)	0,31	Weight (g)
Validità del prodotto	3 Anni / Years	Shelf life

REF	Sterile R	Colore Colour	Confezione interna Internal packing	Scatola / Box		
				Quantità Quantity	Dimensioni Dimensions	Peso (Kg.)
1202/E		Giallo Yellow	Sacchetti da 1000 pz Bags of 1000 pcs	10.000 pcs (10 x 1.000 pcs)	40 x 25,2 x 29 cm 0,029 m ³	3,6
1202/E*		Giallo Yellow	Sacchetti da 1000 pz Bags of 1000 pcs	25.000 pcs (25 x 1.000 pcs)	55,5 x 42,5 x 34 cm 0,087 m ³	8,9
1202/EN		Neutro Neutral	Sacchetti da 1000 pz Bags of 1000 pcs	10.000 pcs (10 x 1.000 pcs)	40 x 25,2 x 29 cm 0,029 m ³	3,6
1202/E/SG	√	Giallo Yellow	Sacchetti da 5 pz Bags of 5 pcs	1.000 pcs (200 x 5 pcs)	29,3 x 17,5 x 24 cm 0,012 m ³	1,1
1202/E/SG/CS	√	Giallo Yellow	Confezione singola Individually wrapped	500 pcs	29,3 x 17,5 x 24 cm 0,012 m ³	0,7
4202/E		Giallo Yellow	Rack da 96 pz Rack of 96 pcs	960 pcs (10 x 96 pcs)	50,5 x 14,5 x 13 cm 0,010 m ³	1,9
4202/E/SG	√	Giallo Yellow	Rack da 96 pz Rack of 96 pcs	960 pcs (10 x 96 pcs)	50,5 x 14,5 x 13 cm 0,010 m ³	1,9
1602		Giallo Yellow	Piastrine refill 96 pz Trays refill of 96 pcs	480 pcs (5 x 96 pcs)	45,5 x 13 x 9 cm 0,005 m ³	0,6

DESTINAZIONE D'USO / INTENDED PURPOSE

La destinazione d'uso è "Per usi generici di laboratorio", dispositivi di preanalitica utilizzati per la preparazione di campioni biologici umani da testare in vitro per esami diagnostici. Unicamente per uso professionale.

Dispositivi fabbricati con Sistema Qualità conforme alle norme UNI EN ISO 9001 e UNI CEI EN ISO 13485.

The intended purpose is "For generic laboratory uses", pre-analytical devices used for the preparation of human biological samples to be tested in vitro for diagnostic examinations. Only for professional use.

Devices manufactured with Quality System compliant with the UNI EN ISO 9001 and UNI CEI EN ISO 13485 standards.

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS (UNI EN CEI ISO 15223-1)



Data di produzione
Date of manufacture



Data di scadenza
Use-by date



Lotto
Batch code



Codice articolo
Catalogue number



Fabbricante
Manufacturer



Monouso
Do not re-use



Utilizzare a confezione integra
Do not use if package is damaged



Proteggere dall'umidità
Keep dry



Non esporre ai raggi del sole
Keep away from sunlight



Non sterile
Non-sterile



Sterile irradiato
Sterilized using irradiation



Apirogeno
Non-pyrogenic



Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy

Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92

E-Mail: info@aptaca.com – Website: www.aptaca.com

AVVERTENZE PER L'USO / OPERATING INSTRUCTIONS

- Destinato esclusivamente ad uso professionale -

- For professional use only -

L'eventuale presenza di scala graduata è da intendersi a scopo indicativo e senza funzione metrologica

Non variare la destinazione d'uso. In caso di dubbio circa la destinazione d'uso, Vi preghiamo di contattare il Fabbrikante.

Prima dell'utilizzo controllare la perfetta chiusura del dispositivo se applicabile

Manipolare utilizzando dispositivi di protezione individuale: pericolo di contaminazione

Non utilizzare il Dispositivo in caso di evidenti segni di rottura, lesioni, fessurazioni che potrebbero comprometterne il corretto uso

Non avvicinare il Dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare

Non utilizzare e smaltire il Dispositivo scaduto o con la confezione non integra

Non riutilizzare: Dispositivo monouso. L'eventuale riutilizzo potrebbe causare la contaminazione del campione.

Nel caso di dispositivo sterile o asettico: stato microbiologico garantito a confezione integra. Non ri-sterilizzare

Utilizzare il Dispositivo unicamente con accessori compatibili e/o in dotazione (tappi, supporti, ecc.)

Non esporre direttamente ai raggi solari; proteggere dall'umidità (U.R. max 75% a 26°C)

Conservare in luogo asciutto, temperatura min. -10°C (14°F) max +50°C (122°F)

Smaltire secondo le normative vigenti, pericolo di infezione.

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.

Any presence of a graduated scale is intended for indicative purposes and without a metrological function.

Do not vary the intended purpose of the device. Please contact the Manufacturer in the event of doubts concerning the intended purpose.

Before use check the perfect closure of the device if applicable.

Handle using personal protective equipment: risk of contamination. Do not use the Device in case of evident signs of breakage, injuries, cracks that could compromise its correct use.

Keep out of flame or heat sources which might damage the device.

Do not use after expiry date or if packing is opened.

Do not re-use: Disposable Device. Any reuse could cause sample contamination.

If sterile or aseptic Device: Microbiological status in undamaged pack.

Do not re-sterilize.

Use the Device only with compatible and / or supplied accessories (caps, supports, etc.)

Do not put under direct sun rays; store in a dry, cool place (U.R. max 75% at 26°C)

Store in dry place, temperature range: min. -10°C (14°F) max +50°C (122°F)

Disposal according to applicable regulations, risk of infection.

Before use with particular substances check the resistance/compatibility chart in our catalogue.

Tutti gli strumenti e i nomi dei produttori citati nella presente scheda tecnica sono marchi dei rispettivi proprietari e sono utilizzati all'unico fine di riferimento.

All instruments and names of Manufacturers mentioned herein are the trademarks of their respective Companies and are used for reference purposes only.

**EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY
DÉCLARATION CE DE CONFORMITÉ · DICHIARAZIONE CE DI CONFORMITÀ**

Name und Adresse des Herstellers: / **BOEN HEALTHCARE CO., LTD**
Name and address of the manufacturer: / **Unit 602, International Center, No.535, Shenxu Road,**
Nom et adresse du fabricant: / **Suzhou, 215021, Jiangsu, China**
Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **Gilson Pipette Tips**
the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / **Common/Others IVD**
of class: / **(Devices of NOT Annex II and NOT self-test)**
de la classe: /
di classe:

(IVDD, Artikel 9 Absatz 1) nicht Teil der Liste A und B von Anhang II sein / (IVDD, Article9(1)) not be part of list A & B of annex II
(IVDD, article 9, paragraphe 1) ne fait pas partie de la liste A et B de l'annexe II / (IVDD, articolo 9, paragrafo 1) non fanno parte dell'elenco A e B
dell'allegato II

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 98/79/EG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 98/79/EC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 98/79/EC et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 98/79/EC e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Anhang III (voraussichtlicher Punkt 6) der IVDD 98/79 /**
Conformity assessment procedure: / **EG Annex III (expect point 6) of IVDD 98/79/EC**
Procédure d'évaluation de la conformité: / **Annexe III (sauf le point 6) de l'IVDD 98/79 / CE**
Procedura di valutazione della conformità: **Allegato III (aspettarsi il punto 6) dell'IVDD 98/79 / CE**

Registrier-Nr.: /
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: /
Notified Body: /
Organisme notifié: /
Organismo notificato:

Suzhou, 201.05.26

Ort, Datum / Place, date /
Lieu, date / Luogo, data

CE

General Manager

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

