Area	**Processing instructions (reusable medical devices) – ISO 17664 / *Condizionamento dei dispositivi medici riutilizzabili***		
	Manufacturer / *Fabbricante*: LED SpA	**Method / *Metodo*:** IA-ISO17664A_IT	**Symbol / *Simbologia*:**  *Number of cycles varies from single product (see packaging)*
A	**Device(s) / *Dispositivo (i)*:**	Electrodes, cables, pliers, autoclavable handpieces,probes.	
B	**Spaulding Classification (Annex C) / *Classificazione (Allegato C)***	Handpieces, Electrodes, Pliers, Probes: CRITICAL USE Cables: NON-CRITICAL USE	
C	**Information-General / *Informazioni-Generalità***	Instruments must not be used without previously being cleaned, didinfected and sterilized. Effective clean ing and d isinfection is a p recondition fo r an effective sterilizatio n o f instruments. Remove the electrodes before cleaning. Observe that only sufficient instruments and product-specified valid methods for cleaning, disinfection and sterilization are used and that the valid parameters with each cycle. Observe th e valid leg al regulatio ns of th e country an d t he regu lations for hygiene of the hospital/clinic. Do not sterilize electrodes and handle bunched together! Every exceeding further application falls within the responsability of the user. Surgical handles and electrodes can be cleaned in the instruments washing machine. It i s i mpoerative t hat t he data of t he di sinfection a gent m anufacturer be ad hered t o. Mechanical pre-cleaning of the knife electrodes and the needle electrodes can be made the same as with conventional surgical electrodes.	
D	**WARNINGS / *AVVERTENZE***	**CAUTION** Do not sterelize in hot air! **INFORMATION** Gas sterilazion! Owing to the fact that the outwards ventilation times were not evacuate for this product gas sterilazion is not recommended	
E	**Limitations on processing**	Repeated processing has effect on these instruments. The amounnt for reapplication of the individual components is, with a s terilization time of 20 minutes and with a sterilization temperature of 134°C, as follows: # Handle/ cable: up 100 times # Argon electrode: up 75 times # Electrodes / forceps: up to 30 times. # Flexible Argon probe: up 20 times	
F	**Note / *Nota*:**	Although the Spaulding Classification is different for the devices, these are part of the same family of products and have the same processes.	

Area	INSTRUCTIONS / *ISTRUZIONI*		
	Process / *Processo*	**Process step / *Step del processo***	**Description, instructions, cautions / *Descrizione, istruzioni, avvertenze***
G	**Initial treatment at the point of use / *Trattamento iniziale nel punto di utilizzo***	Remove contaminauion/ *Ammollo* **(G0)**	Soaking must be made immediately after application (within a maximum of 2 h ours). For this only use al dehyde f ree disinfection a gents (otherwise fixing of blood contamitation) w ith tetsed effectiveness (e.g. DGHM or FDA Approval, respectively CE certification mark) which are suitable fo r i nstrument d isinfection and wh ich are co mpatible with th e insruments. For preliminary removal of dirt residue it is possible, if necessary, to use plastic fleece material or plastic cleaning brush. CAUTION: T he applied disinfection a gent used for s oaking i s only for personnel protection and cannot, after im plemented cleaning, replace the dosinfection sequence carried out later.
		Containment and trasportation / *Contenimento e trasporto* **(G1)**	No particular requiremements. It i s recom mended t hat i nstruments are reproces sde as soon as is reasonably pratical following use.
H	**Preparation before cleaning / *Preparazione prima della pulizia***	Disassembly/ *Smontaggio*	Dismountable instruments ar e t o be di sassembled fo r f urther cl eaning according to the operating instructions.
I	**Cleaning: Automated / *Pulizia: automatizzata***	–	A cleani ng m achine m ethod s hould be used f or cl eaning (cl eaning equipment). C leaning by hand is not recommended due to the distinctly lower effectiveness. LED rec ommends the use of neutral to lig ht al kaline cl eaning ag ent, respectively cleaning and disinfection agent, which does not contain any critical ingredients (depending of concentration). Preferably alcoholic and/or aldehyde co ntents sh ould be use d beca use the materials used are less likely to be affected. When alkaline cleaning a gents are use d (pH 9.5-11 .5) it is p ossible th at discolourintg will take place on the metallic surface. This does n ot cause t he p roduct t o be i noperable. Strong al kaline cleaning agents (pH> 11.5) are to be avoided. The su itability o f th e products for effective cleaning was prov en with a machine m ethod (90° C , 5 minutes) using an alkaline c leaning a gent with a su rface-acting additiv e (ANIOSYME DD1 / n eodisher® MediClean strong). The application of other (or non-equivalent) cleaning agents is m ade o utside th e area of respo nsibility o f th e man ufacturer. Only cleaning agents which have a proven effectiveness are permitted to be use d and whic h are com parable with th e ap plied syste m (clean ing agent) in the available examination. When selecting the applied cleaning agent system it is to be observed: # that is basically suitable for cleaning instruments, # that the chemicals used are compatible with the instruments.
J	**Cleaning: Manual / *Pulizia: manuale***	Not applicable. *Non applicabile.*	Cleaning by h and is not reco mmended d ue to the d istinctly lower effectiveness.

K	**Disinfection / *Disinfezione***	Thermal and / or chemical *Termica e/o chimica*	A cleaning machine method should be used for disinfection (disinfection equipment). Cleaning by hand is not recommended due to the distinctly lower effectiveness. LED recommends the use of neutral to light alkaline cleaning agent, respectively cleaning and disinfection agent, which does not contain any critical ingredients (depending of concentration). Preferably alcoholic and/or aldehyde contents should be used because the materials used are less likely to be affected. When alkaline cleaning agents are used (pH 9.5-11.5) it is possible that discolourintg will take place on the metallic surface. This does not cause the product to be inoperable. Strong alkaline cleaning agents (pH> 11.5) are to be avoided. The suitability of the products for effective disinfection was proven with a machine method (90° C, 5 minutes) using an alkaline cleaning agent with a surface-acting additive (ANIOSYME DD1 / neodisher® MediClean strong). The application of other (or non-equivalent) disinfection agents is made outside the area of responsibility of the manufacturer. Only cleaning agents which have a proven effectiveness are permitted to be used and which are comparable with the applied system (disinfector agent) in the available examination. When selecting the disinfector it is to be observed # that the disinfector has a certified effectiveness (e.g. DGHM or FDA Approval, resp. CE certification mark according to EN ISO 15883), # that as far as possible a tested program for thermal disinfection (at last 5 min at 90°C for A0 – value>3000) is used (with chemical disinfection there is a danger of disinfectant residue on the instruments), # that the program used is suitable for the instruments and contains sufficient rinsing cycles, # that only sterile or germ-free (max. 10 germs/ml) and endotoxinfree (max. 0.25 endotoxin units/ml) rinsing water is used, # that the air used for drying is filtered # that the disinfector is regularly maintained and inspected. When selecting the applied cleaning agent system it is to be observed: # that is basically suitable for cleaning instruments, # that, as long as no thermal disinfection is used, additionally a suitable disinfection agent with certified effectiveness is used (e.g. DGHM or FDA Approval, resp. CE certification mark) and that this is compatible with the applied cleaning agents, # that the chemicals used are compatible with the instruments. It is imperative that the data given by the manufacturer of the cleaning agent and disinfection agent concerning the specified concentrations and effectiveness times be adhered to. Sequence: 1. Place the instruments into the disinfector. Ensure that the cable is not bent or squeezed. 2. Start the program 3. Remove the instruments from the disinfector after the program has finished. 4. Check and pack as far as possible immediately after removal (after additional drying at a clean location) If necessary blow out with filtered compressed air. Only dry the products with compressed air (< 3 bar) in order to avoid possible damage.
L	**Drying / *Asciugatura***	–	If necessary blow out with filtered compressed air. Only dry the products with compressed air (< 3 bar) in order to avoid possible damage.
M	**Maintenace, Inspection and testing / *Manutenzione,***	–	Check the products for operation as well as visual damage according the corresponding operating instructions. LED recommend that with moveable or swivelling parts (e.g. foceps) instrument oil should not be used (excaprion: surgical instruments made of stainless steel) due to the

	ispezione e collaudo		fact that certain plastics tend to swell and owing to the oil even hinder movement.
N	**Packaging /** ***Imballaggio***	–	Before sterilization, the disassembled instruments must be packed into a suitable one-way sterilization packing (single layer or double layer packing) and/or a suitable sterilization container: # according to EN 868 / ISO 11607 # suitable for steam sterilization (temperature resistive uo to 137°C, sufficient steam porosity) # regular maintenance (sterilization container)
O	**Sterilization /** ***Sterilizzazione***	–	Autoclaving. The instruments must only be sterilized in the disassembly condition. Only the following sterilization methods are to be used for sterilization, other sterilization methosd are not pemitted. Steam sterilization # Fractionated vacuum method* (with sufficient product drying) # Steam sterilizer according to EN 13060 resp. EN 285 # According to EN 554 / ISO 11134 valited (valid commissioning and specific product service assessment) # maximum sterilization temperature 134°C (plus tolerance according to EN 554 / ISO 11134) # Sterilization time min. 20 min (at 121°C) resp. 5 to 20 min at 132 /134°C The suitability of the product for effective sterilization was proven with the fractionate vacuum method with the above sterilization times/ temperature. The hot air method for sterilization is basically not to be used (destruction of the instruments). The use of other methods of sterilization (e. g. ethylene oxide, formaldehyde, beam and low temperature plasma sterilization) is outside the responsability of the manufacture. In this case the corrisponding valid standards are to be observed (EN ISO 14937/ ISO 14937, resp. standards for specific methods) and the suitability and principle effectiveness of the method proved (if necessary, including residue inspection of the sterilization material) taking the specific product geometry into consideratin within the scope of validation.
P	**Storage /** ***Conservazione***		Once sterilised, the products must be stored dry and dust-free in their sterilisation packing. The products must also be protected against sun and heat.
Q	**Transportation /** ***Trasporto***		The disassembled instruments are to be assembled according to the corresponding operating instructions for the application. A visual inspection and function tests is to be carried out before every operation
R	**Additional information /** ***Informazioni aggiuntive***	–	* The use of a less effective gravitation method must be ensured by additional validation (if necessary, longer sterilization times required)
S	**Manufacturer contact /** ***Contatto del produttore***	–	LED SpA via Selciatella, 40 04011 Aprilia (LT) ITALY P: +39 06 92 87 0045 F: +39 06 92 87 0046 W: led.it
T	**Date of issue /** ***Data di emissione***	–	ed. 07/2020