COMPASSO

DATA SHEET

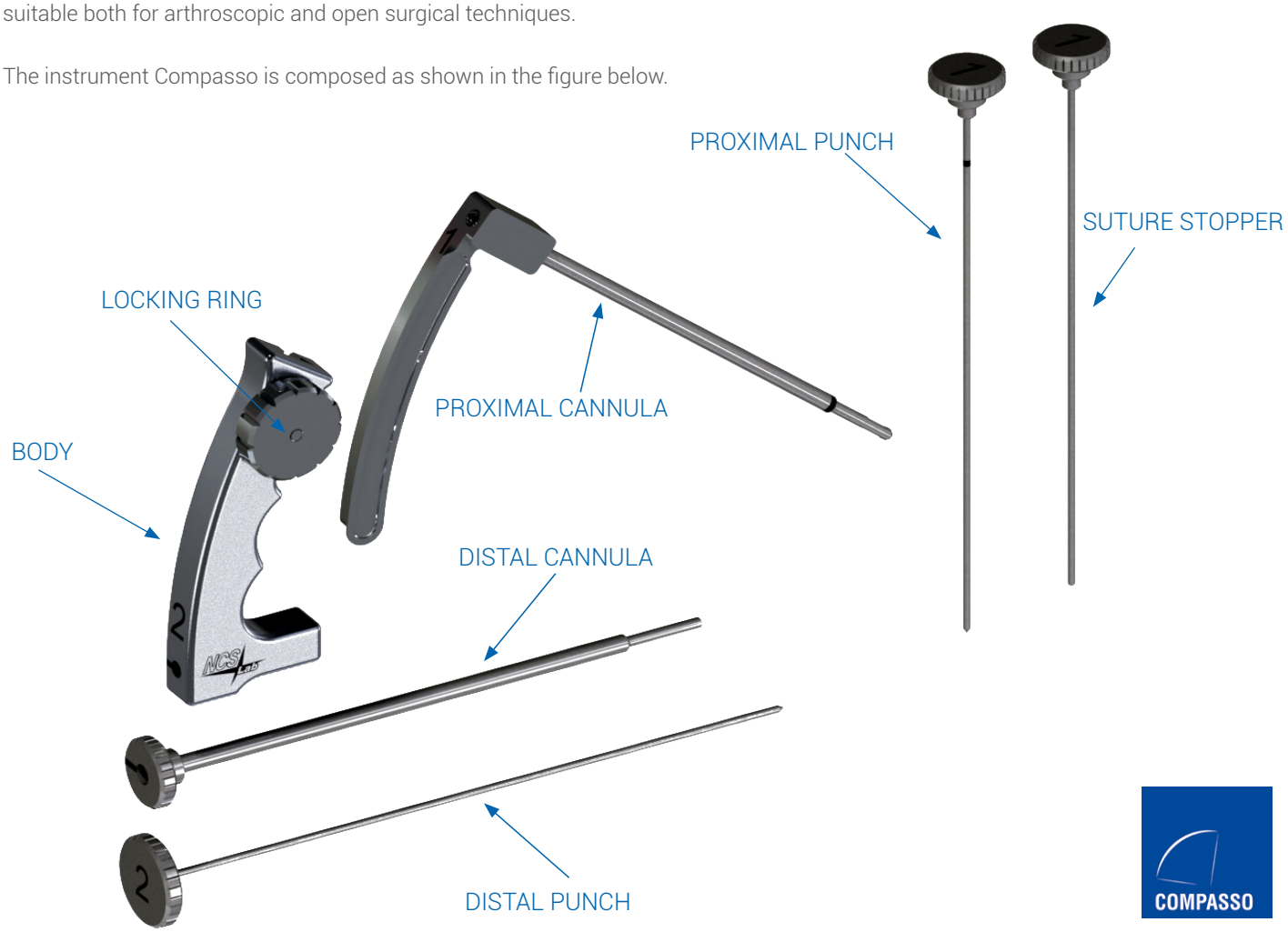
A product by NCS Lab Srl.

DATA SHEET

1. DESCRIPTION AND FEATURES

Ancillary surgical instrument for Elite-SPK and Sharc-FT devices for the treatment of tears to the shoulder rotator cuff.Compasso is suitable both for arthroscopic and open surgical techniques.

The instrument Compasso is composed as shown in the figure below.



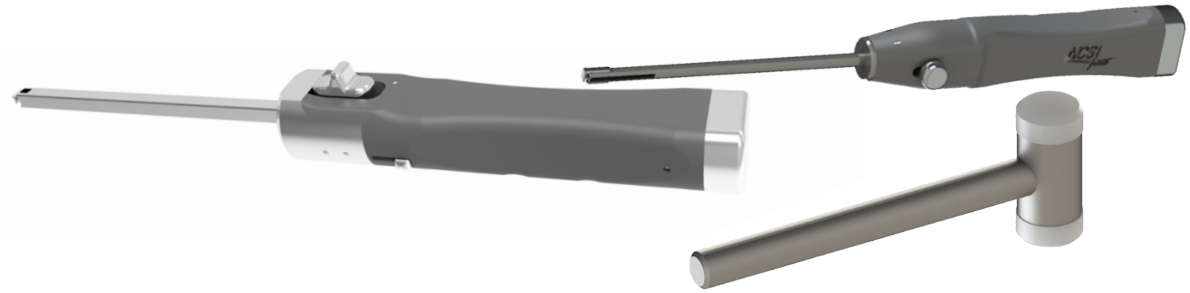
The main body of the instrument allows the choice of the angle best suited to carry out the lateral emergency and avoid problems of impingement due to the excessive protrusion of the acromion.

The proximal cannula is designed to house the guillotine capture system, constituted by the cannula itself and by the suture stopper.

This system helps the recovery of the shipping wire inserted through the distal cannula, in order to allow the dragging of the transosseous sutures.

ACCESSORIES AND TOOLS

The Inserter supports the implant of the medical devices Elite-SPK or Sharc-FT.
The titanium hammer, a calibrated tool that helps the operator to advance the STN needle during the creation of the transosseous tunnel.



2. CODES

CODES	CND	RDM	DESCRIPTION	QUANTITY	PACKAGE
A000130	-	-	Compasso	1	Non sterile
A000122	P091280	1250313	Body	1	Non sterile
A000123	P091280	1250313	Proximal cannula	1	Non sterile
C000499	P091280	1250313	Distal cannula	1	Non sterile
C000503	P091280	1250313	Proximal puncher	1	Non sterile
C000502	P091280	1250313	Distal puncher	1	Non sterile
C000495	P091280	1250313	Suture Stopper	1	Non sterile
P005_AS034_12	K0399	1205097	Hammer TS	1	Non sterile
P005_AS034_02	K0399	900954	Inserter for Sharc-FT	1	Non sterile
P005_AS034_13	K0399	1220833	Inserter for Elite-SPK	1	Non sterile

MANUFACTURER	CLASS	NOTIFIED BODY	STERILIZATION	EXP.
NCS Lab Srl.	I	KIWA-CERMET	-	-

3. CLASS OF RISK: CLASS I

4. MATERIALS

Compasso is made of: Al 7075, AISI 304, AISI 316, AISI 420B, AISI 630, Titanium.

5. PACKAGING, STORAGE AND DISPOSAL

Non-sterile packaging.
The ancillary surgical instrument Compasso, its accessories and complementary tools are supplied non-sterile and must be cleaned and sterilized by steam when opening the packaging and prior to surgical use.

The ancillary surgical instrument Compasso, its accessories and complementary tools must be stored in a dry and clean place, protected from direct sunlight, from insects and extreme conditions of temperature and humidity.

The disposal of the device must be made in accordance to current regulations.

6. INDICATIONS

Read carefully. Failure to follow instructions, warnings and precautions can have serious surgical consequences, compromising the functionality of the device and/or cause injury to the patient.

Compasso is an ancillary surgery instrument for implanting Elite-SPK and Sharc-FT for the treatment of rotator cuff tears. Its use is suitable with arthroscopic and open surgical approach.

NCS Lab Srl recommends appropriate pre-operative training with qualified personnel before the first use of implantable devices Elite-SPK and Sharc-FT.

- The ancillary surgery instrument Compasso and its accessories and complementary instruments are supplied non-sterile and must be cleaned and sterilized by steam when opening the packaging and prior to surgical use.
- Do not alter in any way the instrument Compasso. Such manipulations, in addition to all other interventions and improper use, may result in failure of the product or affect performance causing serious harm to the patient.
- In the case of total or partial damage of Compasso or any of its accessory or complementary instruments, contact your dealer.
- Compasso may only be used in the operating room by competent medical personnel with a degree in medicine and qualified to perform surgery in the area of interest (shoulder).

- Compasso is an ancillary surgery instrument for the implantable devices Elite-SPK and Sharc-FT, for this reason it must be used only for the purpose of implanting such devices or making curved transosseous holes.
- Do not try to implant devices other than its intended Compasso.
- The ancillary surgical instrument Compasso is intended to be used on patients of any age, sex and weight, provided that their physiological growth process of the musculoskeletal system is finished.

7. CONTRAINDICATIONS (NON-EXHAUSTIVE LIST)

- Local or systemic infection, acute or chronic.
- Allergy, hypersensitivity or intolerance (suspected or known) to one or more materials used to manufacture the device.
- Consumption and/or tendency to use and abuse drugs, alcohol or tobacco.
- Patient with an immature skeletal apparatus or excessive bone fragility.

8. PREOPERATIVE PRECAUTIONS

To assess the possibility of using Compasso it is recommended to follow some important preoperative indications:

- Before considering the implantation of a device, the surgeon must take into account the patient's general condition and the effectiveness or the inability to use other surgical or non surgical treatments.
- The surgeon must take into account any previous surgery performed on the patient.
- Each patient with a contraindication should be refused.
- The patient must be informed of the potential risk of failure of the treatment and its consequences.
- Compasso is a reusable surgical instrument provided non sterile: clean and decontaminate the instruments prior to sterilization.
- Before using Compasso, the user must visually check the integrity of the instrument in its entirety.
- Compasso should only be used on patients whose muscle skeletal apparatus development is completed,
- Be especially careful when using Compasso on osteoporotic patients or subjects with bone fragility.
- Before each use, perform all functional checks listed in the table "Functional preoperative controls".

9. INTRAOPERATIVE AND AFTEROPERATIVE PRECAUTIONS

- The surgeon must inform the patient about the post-surgery precautions.
- Do not combine with other manufacturers' devices.
- The surgical technique must be identical to that proposed and described in the surgical technique for Compasso and the surgeon must be familiar with it.
- Place the implant properly, paying particular attention in determining the exit hole (if the system cannot be positioned correctly, you should consider other treatments).
- Choose the right approach, a proper number of sutures and not exceeding 3 and place the implant correctly (if the system cannot be positioned correctly, you should consider other treatments).
- The surgeon must know the mechanical properties and limits of the instrumentation and devices used.
- Radiation protection: the surgeon will take all necessary measures to protect against radiation caused by intraoperative fluoroscopic control of the correct positioning of the implants.
- The implants are for single use only.

10. FUNCTIONAL PREOPERATIVE CONTROLS

Functional preoperative controls
The wire stopper slides without seizure in the proximal cannula.
The Punchers slide without seizures in their cannulas.
Mobility control between the main body and the proximal cannula.
Check that the inserter is not damaged and it is easy to pair it with the implantable devices Elite-SPK or Sharc-FT.

In the event that one or more **non-compliances exist** with the above checks **do not use the ancillary instrument Compasso** conversely NCS Lab disclaims any liability.

11. FACTORS THAT MAY AFFECT THE LIFE OF THE INSTRUMENTATION (NON-EXHAUSTIVE LIST)

- Bumps and falls.
- Acid attacks.
- Cleaning and sterilization done with unsuitable products or tools.
- Alterations in the assembly of components and mechanical parts.
- Replacement of components with non original or non belonging parts.

Parts	Possibie accidents	Damages
Suture Stopper	Forcing	Extremity ruined, loss of straightness.
Proximal cannula	Drop, Forcing	Bending, loss of alignment, extremity ruined.
Distal cannula	Drop, Forcing	Bending, loss of alignment.
Body	Drop, Forcing, Wasting	Loss of corners of the template, limited slip or obstruction of the mobile component, difficulty or impossibility of tightening the locking system.
Inserter	Drop, Wasting	Difficulty or impossibility in supporting the implantable device Elite-SPK and Sharc-FT before the implant, difficulty or impossibility in removing the implantable device Elite-SPK and Sharc-FT after the implant.
Punchers	Drop, Forcing	Bending, limited slipping or obstruction of the mobile component inside the cannula, loss of alignment.

In the event of total or partial damage to the ancillary surgery instrument Compasso contact your dealer for repair or substitution.

12. CLEANING AND STERILIZATION OF ANCILLARY INSTRUMENTATION

The ancillary instrument Compasso is supplied non-sterile, therefore it must be completely cleaned and sterilized in every part as soon as possible, after every use.

Thoroughly clean long and narrow cannulations, and blind holes. We recommend the use of detergents with neutral pH. Follow the manufacturer's instructions of the detergent for correct dilution, concentration, temperature, exposure time and water quality.

Do not use abrasive cleaning devices.

Whenever possible, use a washer/disinfection system (based on ISO 15883) for implants, instruments and cases. Do not overload the washing baskets for ultrasonic cleaning and washing/disinfection system.

CLEANING PREPARATION	Disassemble the ancillary surgery instrument Compasso into its component parts. Remove residues with a cloth or disposable paper.
CLEANING: AUTOMATED ULTRASONIC BATH	The components of the instruments must remain in the ultrasonic bath for the required time and in the manner recommended by the manufacturer of the tank. The wash cycle usually lasts from 5 to 7 minutes. All parts must be totally submerged by the washing solution. Do not insert components made of different metals (stainless steel, chrome-plated instruments, copper, etc.) In the same cleaning cycle. Often change the washing solution, at least as recommended by the manufacturer of the ultrasonic tank used. Thoroughly rinse the instruments with water after cleaning in an ultrasonic cleaner, to remove the residues of the washing solution.

CLEANING: MANUAL	Most manufacturers of surgical instruments indicate the ultrasonic cleaning method as the best and most effective way to clean these instruments, in particular those fitted with hinges, locks and other moving parts. If ultrasonic cleaning is not possible we recommend the following guidelines: Use toothbrushes rigid plastic, nylon, etc; Do not use steel wool or metal brushes; Use only detergents neutral pH; Carefully brush the most delicate instruments and if possible wash, clean and sterilize these instruments separately; Clean with care narrow Cannulations and blind holes; Make sure that the entire surface of the instrument is perfectly clean; After brushing tools rinse with running water; During rinsing ensure that all parts that have interstices are rinsed perfectly.
DRYING	Immediately after the end of the cleaning and rinsing the components must be completely dried.
STERILIZATION	Autoclave according to the Europea Standard EN285/96 which states: "The duration of maintenance of medical devices to achieve sterility of the same shall not be less than: 15 min at 121°C, 3 min at 134°C". A recommended and sufficient time may be: 6 min at 134°C. At the end of each cycle of sterilization in an autoclave, before the drying cycle, open the door slightly, then proceed with the drying cycle according to the instructions provided by the manufacturer of the appliance. If the door of the autoclave is opened fully before the drying cycle, there would be an abrupt decrease in temperature of the air inside the autoclave, becoming a cause for formation of condensation on the instruments, with the consequent formation of gray spots. Use, however, a cycle suggested by the official pharmacopoeia.
FURTHER INFORMATION	Always use the technique of sterilization/cleaning more suited to allow the tools to be used in the desired condition of use. **Remember that: sterilization does not replace cleaning!** It is always very important to check the proper functioning of the apparatus for sterilization. The possible failure would result mainly in the non-sterility of the instruments treated, with the consequent risk of transmission of pathogens during usage. Secondly, it could result in damage to the objects sterilized, mainly due to the achievement of high temperatures that could lead to the tempering of steels, resulting in a possible loss of mechanical properties of the instruments. Hospitals are responsible for compliance with the cleaning and sterilization. The manufacturer and distributor accepts no responsibility for the cleaning and re-sterilization of equipment, components, or reusable instruments performed by the individual or hospital.

The ancillary surgical instrument Compasso, its accessories and complementary tools have no sterilization limits and if necessary can be repaired.

It is recommended to clean, decontaminate and sterilize the instrumentation before sending it for repair.

13. DISCLAIMER

This document is not a surgical technique and should only be considered as a set of technical instructions on how to use the described instruments.

Compasso may only be used in the operating room by competent medical personnel with a degree in medicine and qualified to perform surgery in the area of interest.

NCS Lab Srl. recommends appropriate pre-operative training with qualified personnel before the first use of Compasso and of the

implantable devices Elite-SPK and Sharc-FT.

14. MANUFACTURER:

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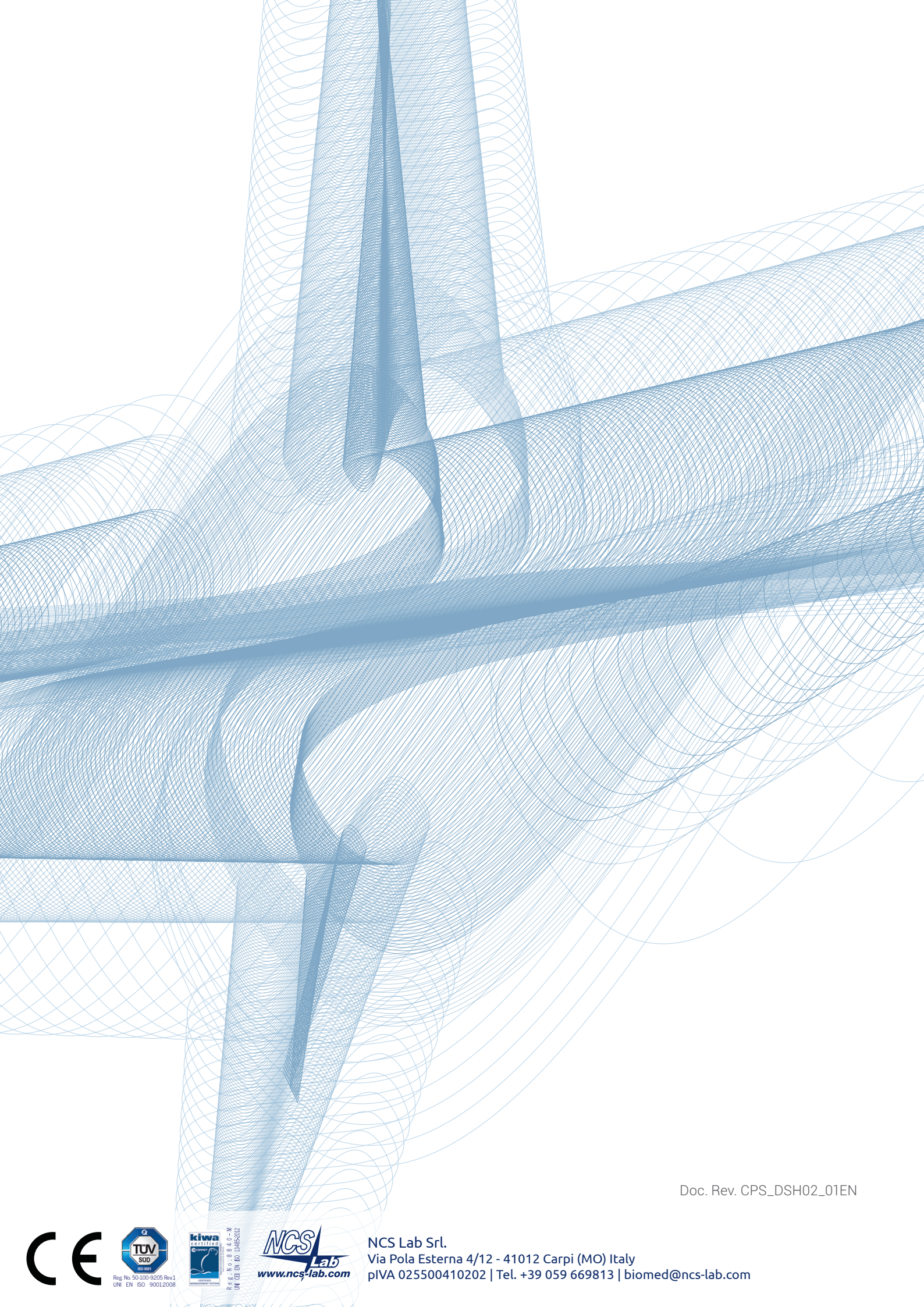
15. DEALER:



Doc. Rev. CPS_DSH02_01EN

Reg. No. 50-100-9205 Rev.1
UNI EN ISO 9001:2008

Reg. n. 8 4 0 - M
UNI CEI EN ISO 13485:2012

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