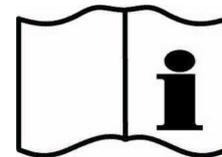




RENZ FOR QUALITY

Modell HighTech



Instructions for use for Stainless Steel Spray Gun Systems*

SRN (Single Registration Number)

DE-MF-000007646

BASIS UDI-DI (according to Annex VI Part C)

42607448364208Q9



<https://www.rfq.de/de/Produkte/Reinigungspistolen/Edelstahlpistolen>

- REF** 64-20820-00 - 64-20820-52 Compressed air SSSGS-Set with quick-lock coupling
- REF** 64-20810-00 - 64-20810-02 De-ionized water SSSGS-Set / Drinking water SSSGS-Set with quick-lock coupling
- REF** 64-20820-70 - 64-20820-90 Compressed air SSSGS-Set with hose fitting
- REF** 64-20810-70 - 64-20810-90 De-ionized water SSSGS-Set / Drinking water SSSGS-Set with hose fitting

1. Purpose of use for the cleaning gun

REF 64-20820-xx

Compressed air SSSGS-Set with quick-lock coupling or hose fitting

For blow-cleaning of contaminated medical devices with medical compressed air with up to 0.5Mpa (= 5bar).

REF 64-20810-xx

De-ionized water SSSGS-Set / Drinking water SSSGS-Set with quick-lock coupling or hose fitting

For rinsing contaminated medical devices with cold de-ionized / drinking water with up to 0.5Mpa (= 5bar).

* **Stainless Steel Spray Gun System**, hereinafter referred to as **SSSGS**

(The hyphens in the article numbers are inserted for better readability)

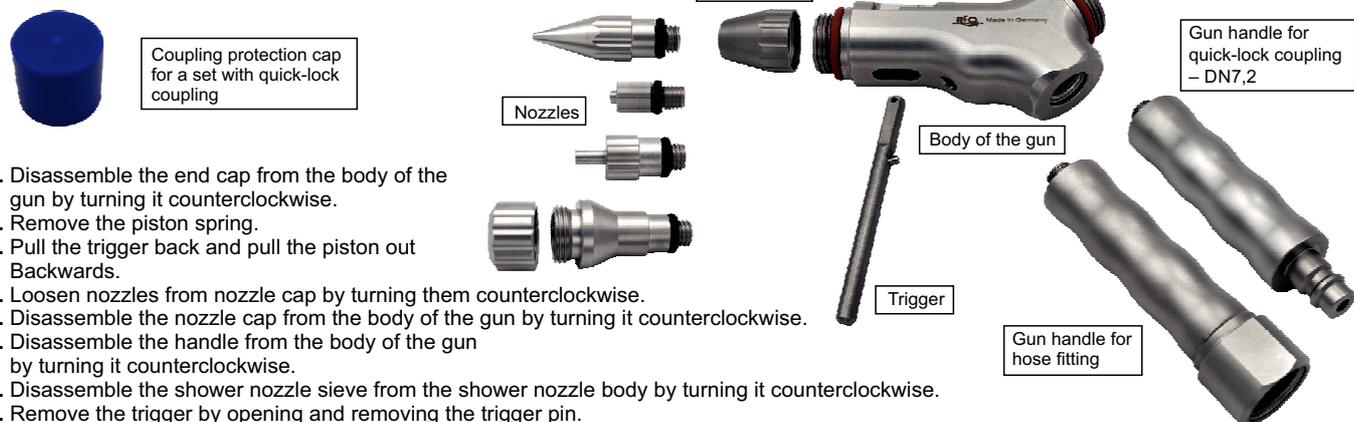
2. Reprocessing intervals

The cleaning gun and accessories (nozzles, luer-lock connector, coupling protection cap and hose end cap) are to be cleaned and sterilized prior to the first use! The cleaning gun must be disassembled for cleaning and sterilization! The reprocessing intervals are to be determined by the user depending on the purpose of use and the frequency of the resulting contamination and soiling of the SSSGS itself. When contaminated, the cleaning gun must be reprocessed together with all accessories! The parts of the "hose unit" (hose, coupling, hose connection adapter) are not medical devices and can not be reprocessed in case of contamination of the pumped medium.

We therefore recommend to carry out microbiological tests, depending on the purpose of use.

3. Disassembly of the cleaning gun

(It is not necessary to remove the fitted O-ring seals)



1. Disassemble the end cap from the body of the gun by turning it counterclockwise.
2. Remove the piston spring.
3. Pull the trigger back and pull the piston out Backwards.
4. Loosen nozzles from nozzle cap by turning them counterclockwise.
5. Disassemble the nozzle cap from the body of the gun by turning it counterclockwise.
6. Disassemble the handle from the body of the gun by turning it counterclockwise.
7. Disassemble the shower nozzle sieve from the shower nozzle body by turning it counterclockwise.
8. Remove the trigger by opening and removing the trigger pin.

4. Reprocessing of the cleaning gun, nozzles, luer-lock connector, coupling protection cap, nozzle rack and the hose end cap. (It is not necessary to remove the fitted O-ring seals)

Cleaning by qualified specialist staff in compliance with the guidelines for cleaning and disinfection following the latest RKI (Robert Koch Institute) recommendations (www.rki.de). The specifications of the manufacturer of the cleaning agents (product data sheets and safety data sheets) are to be met. Furthermore, appropriate protective clothing compliant with the requirements of the competent employer's liability insurance association shall be worn for reprocessing. The cleaning validation of the SSSGS (Report number 8739 and 8740) was performed with the following preparation and cleaning equipment:

Cleaning agents for instruments: neodisher MediClean forte (alkaline cleaning agent with surfactants, pH 10,4 – 10,8 in de-ionized water) manufactured by Chemische Fabrik Dr. Weigert GmbH & Co.KG – Hamburg Web: www.drweigert.de

4.1 Pre-cleaning: Cleaning agents for instruments: neodisher MediClean forte 2% solution up to 40°C maximum

- a. Disassemble the SSSGS-Set (see "3. Disassembly of the cleaning gun"). Place the parts of the cleaning gun in a basket with the neodisher MediClean forte 2% cleaning solution and clean all visible stains with a soft brush or cloth under the liquid's surface.
- b. If soiled heavily (e.g. protein exposure like blood), the SSSGS parts must remain in the trough filled with the cleaning solution without bubbles to soak for at least 15 minutes. The cleaning solution is to be renewed at least daily or immediately if contamination is visible.
- c. Rinse and flush all instrument parts under cold running water (drinking water quality) which is free from pathogenic germs before the subsequent ultrasonic cleaning.

4.2 Ultrasonic cleaning: Absolutely necessary!

Cleaning agents for instruments: neodisher MediClean forte 2% solution up to 40°C maximum, 10 minutes duration

The ultrasonic device must be suitable for the cleaning of medical instruments and should have a frequency of 35-40kHz. The cleaning time increases when using devices with a higher frequency! Important: As soon as the ultrasonic cleaning device is turned on, the cleaning solution in the ultrasonic bath heats up. To avoid the cleaning solution heating up to more than 40°C additional heating in the ultrasonic bath should be avoided. All SSSGS-Set parts must be fully immersed in the cleaning solution and all hollow spaces must be filled. Ultrasonic baskets may not be overloaded as this may create sonic shadows. The cleaning effect cannot be guaranteed in this case! The cleaning solution must be renewed at least daily or immediately if contamination is visible.

4.3 Rinsing - Flushing

Rinse and flush all SSSGS-Set parts with cold water (drinking water quality) which is free from pathogenic germs. Check the cleaning result!

- 4.4 **Subsequently machine cleaning of the individual parts with:** Cleaning and disinfection device type Miele G7835 CD – Program Des-Var-TD. Place the disassembled SSSGS-Set parts in the respective basket of the cleaning and disinfection device and connect all accessible hollow spaces to the hollow space flushing system of the cleaning and disinfection device. Close the door, select the appropriate program and start the cleaning and disinfection device.

(Recommendation: Sterilization tray - Article number 64-20850-59).

Program schedule:

| | | | |
|----------------------|--|----------|------------|
| Pre-rinse | with cold water of drinking water quality | 10°C | 1 minutes |
| Cleaning | Neodisher Mediclean forte, alkaline 0,5% (water of drinking water quality) | 55+/-5°C | 5 minutes |
| Neutralisation | Neodisher Z 0,1% (water of drinking water quality) | 10°C | 2 minutes |
| Rinsing | with deionized water | 10°C | 1 minutes |
| Thermal disinfection | with deionized water | >90°C | 5 minutes |
| Drying | Temperature setting on the unit | 80°C | 30 minutes |

4.5 Removing the cleaned SSSGS-Set parts from the cleaning and disinfection device

Remove the cleaned SSSGS parts from the cleaning and disinfection device after the cleaning process has been completed. Wear disposable gloves to avoid further contamination. Check cleaning- and drying status of the SSSGS parts. If they have not been cleaned completely the appropriate cleaning steps are to be repeated respectively a final drying process is to be performed by using compressed air for medical purposes.

4.6 Preparing the SSSGS for steam sterilization

Check the completely cleaned and dried instrument parts for possible defects (see 4.8). Sterilization must be performed in a single transparent sterilization package according to European Standard EN 868-5.

4.7 Sterilization of the SSSGS parts

Steam sterilization: Sterilizer class B EN13060 - Fractioned fore-vacuum – temperature 134°C – minimum dwell time 5 minutes. The guidelines of the sterilization device manufacturers are to be observed before loading the sterilization chamber. The shelf life after sterilization depends on the storage container used. Please observe the manufacturer's information! Do not ever reuse the SSSGS after contamination with pathogens which cannot be killed by the sterilization procedure.

4.8 Checking the SSSGS parts after sterilization

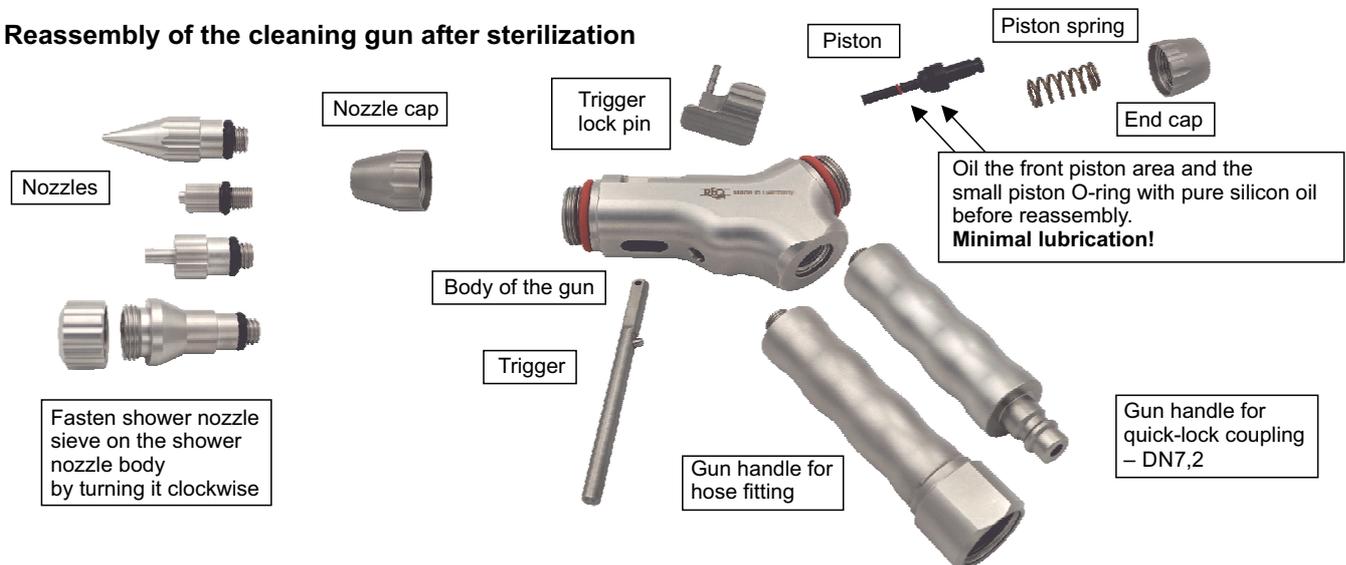
The SSSGS must not be used if:

- the SSSGS is not properly cleaned and sterilized.
- parts of the SSSGS are bent, have corroded or have defect threads.
- O-rings or sealing discs are missing or damaged.

The use of the SSSGS is at the user's own responsibility.

If defects are found during the inspection, even if they are not mentioned here, the SSSGS is not be used.

5. Reassembly of the cleaning gun after sterilization



Please check if all O-rings shown in the picture are present and undamaged before reassembling the gun!
Screw all parts in place finger-tight by clockwise rotation.

Use of the cleaning gun with compressed air and Water:

1. Lubricate the front end of the piston and the small piston O-ring with pure silicone oil prior to the assembly!
Only minimal lubrication! If you insert the piston dry the piston seal will be damaged! Then insert the piston into the gun body, position the piston spring onto the piston and screw the end cap to the gun body.
2. Screw the nozzle cap to the front of the gun body and screw the desired nozzle into the nozzle cap.
3. Screw the gun handle into the gun body as far as it will go.
4. Oil the plug nipple of the handle DN7.2 with pure silicone oil if it is difficult to insert it into or remove it from the stainless steel coupling.
5. Insert the trigger into the gun body and fix it using the trigger lock pin and lock it by folding the trigger lock pin down.

Note: The silicone oil supplied is not sterile.

Caution: Oils containing white oil or paraffin oil destroy the sealing rings.

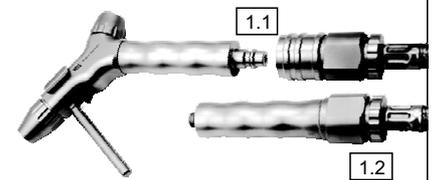
Note: If the piston is difficult to remove from or insert into the gun body despite oiling, the piston o-ring small REF 64-20850-24 needs to be replaced (See parts overview page 7).

Please note: The water respectively compressed air supply line must always be disconnected when the gun is not used or if you want to carry out assembly work on the SSSGS. In this case the pressure in the system is to be relieved through the cleaning gun by activating the trigger. The entire system has to be checked for damages before every opening of the pressure line!
The system has to be checked for leakage if the pressure line has been opened!

6. Cleaning gun sets: 64-20810-xx / 64-20820-xx

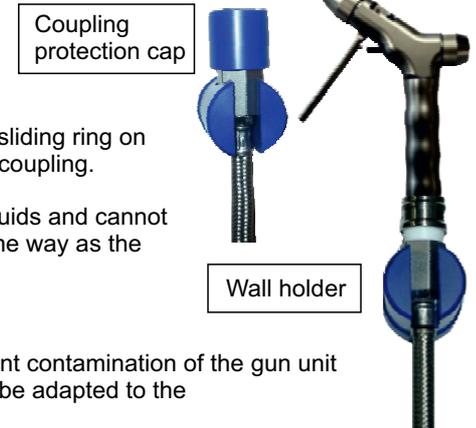
Mounting the cleaning gun with the quick-lock coupling (1.1) / the hose connection (1.2)

- 1.1 Insert the pistol grip with coupling plug DN7.2 straight into the pistol coupling and push it in until it clicks audibly into place.
- 1.2 Screw the pistol grip with hose fitting to the hose connection (1/2" AG).
2. Open the pressure supply line and check the entire system for leakage!



Dismounting the cleaning gun from the quick-lock coupling:

1. First, the pressure supply is to be interrupted if you want to dismount the cleaning gun from the quick-lock coupling again for reprocessing.
2. Relieve the pressure in the hose through the gun by activating the trigger.
3. Press the gun handle into the quick-lock coupling and, at the same time, pull the sliding ring on the quick-lock coupling towards the hose. Then pull the gun out of the quick-lock coupling.
4. Put the sterile coupling protection cap over the gun coupling.
5. The hose must be stored in such a way that it does not come into contact with liquids and cannot be contaminated. The coupling protection cap is cleaned and sterilized in the same way as the cleaning gun parts.



7. Wall holder for the cleaning gun

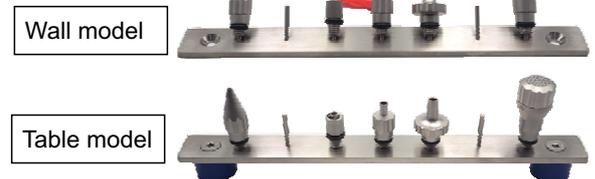
The wall holder for the cleaning gun must be located in an adequate position to prevent contamination of the gun unit while it is not in use. The attachment screw and the raw plug for the wall holder must be adapted to the type of wall and must ensure firm support.

For this reason it is not always possible to use the enclosed mounting accessories.

8. Nozzle stand - Table model / Wall model

Up to 7 nozzles can be attached to the nozzle stand.

The nozzle stand is cleaned and sterilized in the same way as the cleaning gun parts. The reprocessing takes place without nozzles.



9. Installation of the SSSGS - unit

The SSSGS-unit (Cleaning gun, hose, hose fitting, quick-lock coupling) is to be installed by a professional company in accordance with the guidelines applicable depending on the intended use.

10. Hose, quick-lock coupling and hose connection adapter

The hose, hose fittings and hose couplings are not medical devices. The user must replace the hose unit depending on the type of use, state of the hose unit and duration of use.

The usage of the hose unit is prohibited in case of any damage or leakage!

Hose materials and maximum pressure: See under Technical data.

The tube length must be chosen to allow for an admitted bending radius of at least 60 mm during mounting and operation of the tube. In case of curved laying, the tube must be long enough to form an open curve since otherwise the tube will be kinked and destroyed at the connections.

The flexible connection is not to be twisted or kinked in any case.

The hose must not be subjected to any external tension or pressure, neither during assembly nor during use. The installer of the hoses is responsible for the tightness of the connection (hose/connection). As we are not familiar with the geometry and material of the counterparts the sealing material supplied must be checked for suitability by the installer. The warranty will only come into effect in case of professional installation considering all standards and regulations.

11. Safety guidelines and hazard notes for the use of the SSSGS – unit

Before using the unit you must always ensure that all connections of the cleaning gun unit are tightly assembled and are not leaking.

The water- and compressed air supply line must always be disconnected when the gun is not used or if you want to carry out assembly work on the cleaning gun unit. The pressure in the system is to be relieved through the cleaning gun by activating the trigger.

Before every opening of the pressure line, the entire system has to be checked for damages!

When the pressure line has been opened the system must be checked for leakage! The user must be protected from spray (goggles, mask, splash guard, clothing etc.). Furthermore you have to stick to all terms for the usage of the clean gun, provided by your professional association (Employer's Liability Insurance Association).

The nozzles on the cleaning gun must be firmly attached to the nozzle cap.

12. Examination of the SSSGS – unit by the user before its use

It is prohibited to use the SSSGS if:

- The SSSGS - unit is not properly connected.
- The SSSGS - unit is not properly cleaned and sterilized.
- The SSSGS - unit have damages or leaks.
- Parts of the SSSGS - unit are bent, infested with rust or have thread defects.
- O-rings or seal discs are missing or damaged.

The user is responsible for the use of the SSSGS - unit. If any defects should be found during the examination, even if they are not mentioned here, the usage of the SSSGS is prohibited.

13. Technical Data

| | |
|---|---|
| Medium: | Oil-free compressed air / cold water / cold de-ionized water (Depending on the hose material used) |
| Extraction point - max pressure: | Extraction point (=Gun hose connection point) 0,5Mpa (=5 bar) |
| Materials: | |
| Cleaning gun: | Stainless steel 1.4404 / Piston spring Stainless steel 1.4571 |
| Piston: | Plastic - PEEK USP Class VI |
| Nozzles: | Stainless steel 1.4404 - Luer-Lock connector - brass chrome-plated |
| Quick-lock coupling*: | Stainless steel 1.4404 / Springs 1.4571/ Locking pins 1.4310 |
| Seal disc quick-lock coupling / hose: | EPDM with KTW-approval |
| Coupling protection cap: | Plastic with FDA approval |
| Hose connection cap: | Stainless steel 1.4404 |
| Hose connection adapter: | Stainless steel 1.4404 - seal disc: KTW approval |
| Nozzle stand base plate: | Stainless steel 1.4301 / plug-on pins: Stainless steel 1.4310 / feet: Plastic with FDA approval / Mounting screws: Stainless steel 1.4301 |
| Lubricant: | silicone oil (non-sterile) |

Note: The front piston area with the small piston O-ring must be lubricated with silicone oil after each reprocessing. (minimal lubrication)!
The O-rings inside the quick-release coupling are lubricated with silicone oil at assembly.

EPDM O-ring approval:

(cleaning gun, piston, nozzles, attachments, hose cap and quick-release coupling):

EU 65/2011 (RoHS); EC 95/2002 (RoHS); EC 11/2003; FDA; EC 2023/2006; EC1935/2004 article 3; BfR XXI Kategorie 4; ADI free; ACS; WRAS; USP Class VI; UBA; ÖNORM; NSF 61; NSF 51; KIWA; DVGW W270; DVGW W534; EN 681-1; AS/NZS 4020; 3-A Sanitary Standard; GB 4806.11-2016

| | |
|----------------------------------|---|
| Hose for compressed air*: | PVC fabric hose with KTW-C / FDA (21 CFR §170 - §190) (§ 175.300) approval inner diameter 6mm / outer diameter 12mm |
| or | ¹ polyamide spiral hose PA12W -40°C to +90°C (without certificate or test report) inner diameter 6mm / outer diameter 8mm |
| Hose fitting: | ² anodized aluminum - nickel-plated brass with bend protection |
| Hose outlet: | external thread 1/2" |
| Hose inlet: | Open, the appropriate connection must be provided by the operator. |

Hose for drinking water / de-ionized water*: Silicone hose with stainless steel braiding and KTW-A / W270 / W543 approval

| | |
|----------------|--|
| Hose fittings: | Stainless steel 1.4404 |
| Hose outlet: | male thread 1/2" |
| Hose inlet: | 3/8" union nut - seal disc with KTW approval |

***No statement by the manufacturer for reprocessing.**

Water flow rate at 0.35Mpa (=3.5 bar)

| | |
|----------------------|-------------------------|
| Pointed nozzle | approx. 0.75 liters/min |
| Luer lock connection | approx. 5.0 liters/min |
| Hose nozzle | approx.. 6.2 liters/min |
| Shower nozzle | approx. 6.0 liters/min |
| Without nozzle | approx. 6.4 liters/min |

Air flow rate at 0.35Mpa (=3.5 bar)

| | |
|----------------------|-------------------------|
| Pointed nozzle | approx. 35 liters/min |
| Luer lock connection | approx. 230 liters/min |
| Hose nozzle | approx.. 300 liters/min |
| Shower nozzle | approx. 270 liters/min |
| Without nozzle | approx. 350 liters/min |

14. Warranty

1 year for stainless steel parts, piston and hose.

O-rings are wear parts and not covered by the warranty.

Color changes at the plastic elements and damages caused by force are excluded from any warranty.

Warranty and liability claims are only accepted, when you strictly adhered to our delivered instruction manual.

The warranty is excluded if third-party oils are used.

15. Disposal

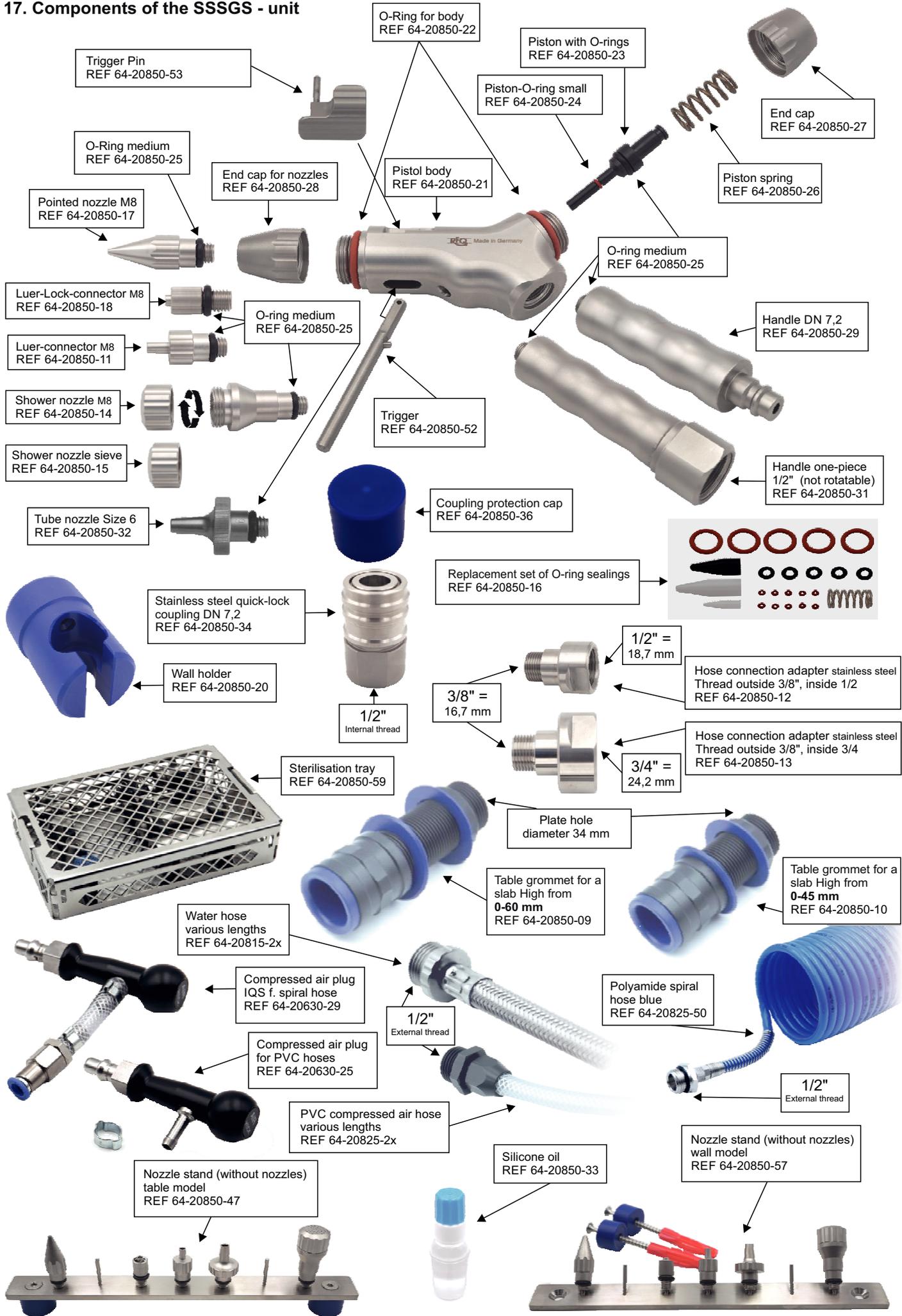
Disposal of the SSSGS - unit according to national law!

16. Directive conformity

This medical device is CE marked according to MDR 2017/745



17. Components of the SSSGS - unit



Notes / Supplements

Requirements for safe, proper use/reprocessing

Fundamentals

Reprocessing utensils must be reprocessed at least every working day!

Safe, proper reprocessing requires a risk assessment.

Risks from water-typical bacteria, such as pseudomonads, legionella etc., must be taken into account.

The effectiveness of a reprocessing method or the reprocessing success must be proven and ensured by appropriate, objective tests (validation). The same requirements apply to outpatient and inpatient facilities. **The operator is responsible!**

Cleaning guns intended for the reprocessing of medical devices and which can be reprocessed must be **completely disassemblable, disinfectable and sterilizable.**

Industrial cleaning guns do not meet these requirements. Certified medical devices are to be preferred!

Cleaning guns intended for the reprocessing of medical devices and which are reprocessable are class 1 medical devices. According to DIN EN ISO 17664, the manufacturer must provide objectively tested (validated) reprocessing instructions and specify all individual steps.

All RfQ stainless steel cleaning guns can be completely disassembled, disinfected and sterilized!

Safe reprocessing is described in individual steps and proven by objective evidence.

Annotation to the "validation" / reprocessing process:

The manufacturer's instructions must include a procedure that documents the reliability (reproducible at any time, traceable, safe) of a reprocessing method.

This includes all manual and, if necessary, mechanical reprocessing steps.

Manual, manual with device support (US cleaning) and mechanical reprocessing methods are suitable.

The employees entrusted with reprocessing must be instructed and demonstrate their expertise.

Explanation of the symbols on the product label

| | | | |
|---|---------------------|---|-----------------------------|
|  | Article number |  | Product designation German |
|  | Quantity |  | Product designation English |
|  | Lot number |  | Instructions for use |
|  | Manufacturer |  | Non sterile |
|  | Date of manufacture |  | Is a medical device |

