

STERILIZATION RECOMMENDATIONS

Name of manufacturer **pro3dure medical GmbH**
 Address of manufacturer **Am Burgberg 13
 58642 Iserlohn
 Germany**

We recommend the following process steps for sterilization of 3D printed parts out of RU-005 GUIDE:

Processing parameters of cleaning

Apparatus	Miele PG 8527
Program name	P43 Normal dosage
Program sequence	Pre-rinse (tap water cold) Cleaning: <ul style="list-style-type: none"> - Neodisher mediclean Forte - Concentration: 5mL/L - Cleaning temperature: 55°C - Cleaning duration: 10MIN Rinse with demineralized water Intermediate rinsing 1 (tap water cold) Intermediate rinsing 2 (1/2 tap water cold, 1/2 demineralized water cold) Final rinsing (demineralized water) Thermal disinfection: 94°C / 10MIN Drying: 115°C / 15MIN

Processing parameters of sterilization

Apparatus	MMM Steam Sterilizer Euro-Selectomat 666-1H
Program name	P02 Universal 134
Program sequence	Evacuation: <ul style="list-style-type: none"> - Pressure (min): 43mbar - Pressure (max): 1498mbar - No of evacuations: 4 Sterilization: <ul style="list-style-type: none"> - Pressure: 3102mbar - Temperature: 134.5°C - Time: 5MIN Drying: <ul style="list-style-type: none"> - Time: 10MIN

The user is solely responsible for carrying out the sterilization and for proving the effectiveness.
 In addition, the information given in the respective instructions for use must be taken into account.