

To whom it may concern

## DECLARATION OF MATERIAL / STEEL CERTIFICATE

We **ELCON MEDICAL INSTRUMENTS GmbH** do hereby confirm that all our products are produced according to EN ISO 13485:2016 including Annex II – excluding Section 4 of Council Directive 93/42/EEC (for all instruments risk class 2a and 2b).

All products are according to DIN EN ISO 14971 (edition 2013/04) for medical devices – application of risk management to medical devices.

The materials used by ELCON MEDICAL INSTRUMENTS GmbH are always corresponding DIN EN ISO 7153-1 for surgical instruments – metallic materials – Part 1 stainless steel (ISO 4153-1:1991, including amendment 1:1999); German Version EN ISO 7153-1:2017-02).

These materials are fulfilling DIN EN ISO 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006); German edition EN ISO 17665-1:2006 and DIN EN ISO 17665-2 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1 (ISO/TS 17665-2:2009); German edition EN ISO/TS 17665-2:2009.

Below we specify our steel analysis report for the main product groups of general surgery instruments according to DIN norm 9002.

| Type of instrument  | Material No.           | Hardness Rockwell |
|---------------------|------------------------|-------------------|
| Scissors            | 1.4034, 1.4117, 1.4028 | HRC 50 – 56       |
| Haemostatic Forceps | 1.4021                 | HRC 40 – 46       |
| Vaginal speculums   | 1.4301                 | NA                |
| Retractors          | 1.4021, 1.4301         | HRC 40 – 46 / NA  |
| Needle Holders      | 1.4021                 | HRC 40 – 46       |
| Tissue Forceps      | 1.4021                 | HRC 40 - 46       |
| Scalpel Handles     | 1.4301                 | NA                |
| Hollowware          | 1.4301                 | NA                |

**Banken:**

Kreissparkasse Tuttlingen (bank code 643 500 70)  
 account no.: 6781  
 Swift-/Bic-code: SOLA DE S 1 TUT  
 IBAN: DE29 6435 0070 0000 0067 81

Deutsche Bank (bank code 653 700 75)  
 account no.: 2 115 160  
 Swift-/Bic-code: DEUT DE SS 653  
 IBAN: DE20 6537 0075 0211 5160 00

Postbank Karlsruhe (bank code 660 100 75)  
 account no.: 62 3924 753  
 Swift-/Bic-code: PBNKDEFF  
 IBAN: DE06 6601 0075 0623 9247 53

Geschäftsführer:  
 Thomas Jakobi, Holger Lücke  
 Handelsregister:  
 Stuttgart HRB 450476

Below we specify the composition of steel

| Material No. | Germany (DIN) | Japan (JIS) | USA (AISI) | C %               | Si ≤% | Mn ≤% | P ≤%  | S ≤%  | Cr %              | Mo %              | V %               | Ni %          |
|--------------|---------------|-------------|------------|-------------------|-------|-------|-------|-------|-------------------|-------------------|-------------------|---------------|
| 1.4034       | X46Cr13       | -           | -          | 0,43<br>-<br>0,50 | 1,00  | 1,00  | 0,040 | 0.030 | 12,5<br>-<br>14,5 | -                 | -                 | -             |
| 1.4028       | X30Cr13       | SUS 420J2   | 420F       | 0,26<br>-<br>0,35 | 1,00  | 1,00  | 0,040 | 0,030 | 12,0<br>-<br>14,0 | -                 | -                 | -             |
| 1.4117       | X38CrMoV15    | -           | -          | 0,35<br>-<br>0,40 | 1,00  | 1,00  | 0,045 | 0,030 | 14,0<br>-<br>15,0 | 0,40<br>-<br>0,60 | 0,10<br>-<br>0,15 | -             |
| 1.4021       | X20Cr13       | SUS 410J1   | 420        | 0,16 -<br>0,25    | 1,00  | 1,50  | 0,040 | 0,030 | 12,0<br>-<br>14,0 | -                 | -                 | -             |
| 1.4301       | X5CrNi18-10   | SUS 304     | 304        | ≤0,07             | 1,00  | 2,00  | 0,045 | 0,015 | 17,0<br>-<br>19,5 | -                 | -                 | 8,0 -<br>10,5 |

ELCON MEDICAL INSTRUMENTS GMBH

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 -Managing Director-

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**Samrin Akbar**  
 -Quality Manager-

09.03.2020

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