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EC DECLARATION

OF CONFORMITY NO. CE-UK-2024143

GGL has examined the product and the related technical file as per Annex II and III of the product(s) and has been assessed according to the Declaration of Conformity as per Annex IV as presented and certifies that the below mentioned product complies with the applicable requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning medical devices ("MDR") for Class I Medical Devices and meet the transposition into national and international laws. All supporting documentations are retained under the premises of the manufacturer. GGL is exclusively responsible for the declaration of conformity. The Directive(s) and Standard or Specification as below.

Hand Automation Surgical **Certificate Holder**

Company Address Capital Road, Near Model Town, Cheema Chowk, Sialkot, Pakistan

Product Name See Annex 1

Classification Class I (Non-Sterile) according to Annex VIII and Article 51 of the

MDR

EC Declaration of Conformity (Annex IV of Regulation **Assessment Route**

(EU) 2017/745)

Examined for Compliance with: Regulation (EU) 2017/745

Reference: The classification rules in Annex VIII and Article 51 of the MDR Relevant Standard(s)/Technical Specification: Regulation (EU) 2017/745 of the European Parliment and of the Council of 5 April 2017 concerning medical devices Harmonized & Applicable Standards References: BS EN 1041:2008+A1:2013, EN ISO 13485:2016, EN ISO 10993-1:2018 This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration Limitations: GGL has liabilities limited to the audit for certification of the products and in case of alteration of the products, not agreed upon by us, this declaration will

Technical File Reference No. Verification Report No.

lose its validity automatically.

CE-UK-2024-HA-84 CE2024.G.UK.90 **Original Registration Date** February 14, 2024 Rome, February 14, 2024 Place, Date of Issue

Expiry Date of the Certificate February 13, 2025



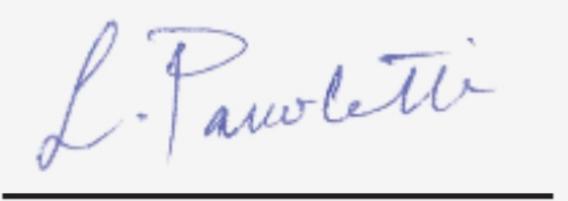


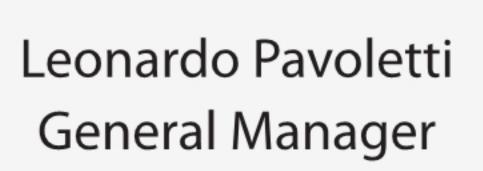


Signed on behalf of GGL Italy Branch:

Italy office: Via di Campo Marzio, 634, 00186 Rome RM, Italy

Web: www.gitchiagroup.com | E-mail: info@gitchiagroup.com







Scheme Manager

General Conditions for Certification Services: This registration was subject to the GGL terms and conditions, auditing and certification procedures. The certificate is subject to regular surveillance audits. To take care of the effectivity of certificate organization should have to successfully pass the audit. While all due care and competence was practiced in carrying out the assessment, GGL accepts only responsibility for the proven gross negligence. This certificate remains the property of GGL. The first certificate and every one copies shall be came or destroyed upon the request by GGL. This document is copy right protected. Content could not be duplicated without the prior written permission of GGL. Any misapplication, modification, deceit and fabrication is unlawful. Head office: 906 Bear Branch Way #208, Wake Forest, NC 27587 United States (Certificate# 202303102201-1)

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EC DECLARATION

OF CONFORMITY NO.CE-UK-2024143

List of product(s) attachment to the declaration of conformity

Manufacturer: Hand Automation Surgical

Annex 1

Sr. No.	Product(s)	Article Number
1	Percussion Hammers and Aesthesiometers	EU-HA-01
2	Scissor	EU-HA-02
3	Probe	EU-HA-03
4	Self-Retaining Retractor	EU-HA-04
5	Sponge and Dressing Forceps	EU-HA-05
6	Obstetrics Tracheotomy	EU-HA-06
7	Hemostatic Forceps	EU-HA-07
8	ENT Surgery Instrument	EU-HA-08
9	Elevator Bone Lever	EU-HA-09
10	Trocar	EU-HA-10
11	Wound Retractor	EU-HA-11
12	Vaginal Speculum	EU-HA-12
13	Biopsy Instrument and Curette	EU-HA-13
14	Cardio-Vascular and Thoracic Surgery	EU-HA-14
15	Needle Holder	EU-HA-15
16	T.C Instrument	EU-HA-16
17	Mallet	EU-HA-17
18	Plaster Instrument	EU-HA-18
19	Suction Instrument	EU-HA-19
20	Micro Instrument	EU-HA-20
21	Neurosurgery and Laminectomy Instrument	EU-HA-21
22	Abdominal Surgery Instrument	EU-HA-22
23	Extracting Forceps	EU-HA-23
24	Root Elevators	EU-HA-24
25	Filling Instrument	EU-HA-25
26	Dental Probe	EU-HA-26
27	Periodontia Instrument	EU-HA-27
28	Curette Scaler	EU-HA-28
29	Diagnostic Explorer and Endodontic Instrument	EU-HA-29
30	Excavator	EU-HA-30



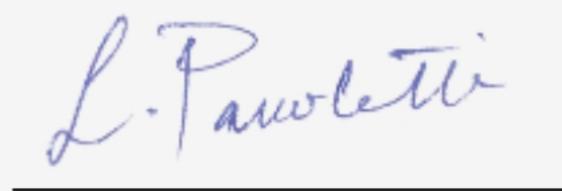
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Blockchain ID

Signed on behalf of GGL Italy Branch:



Leonardo Pavoletti General Manager

Eduardo Ricagni Scheme Manager

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EC DECLARATION

OF CONFORMITY NO.CE-UK-2024143

List of product(s) attachment to the declaration of conformity

Manufacturer: Hand Automation Surgical

Annex 1

Sr. No.	Product(s)	Article Number
31	Mouth Mirror and Handle	EU-HA-31
32	Syringe	EU-HA-32
33	Dental Tweezer	EU-HA-33
34	Rubber Dam Clamp	EU-HA-34
35	Matrix Retainer	EU-HA-35
36	Crown Remover	EU-HA-36
37	Rongeurs	EU-HA-37
38	Bone Elevator	EU-HA-38
39	Bone File	EU-HA-39
40	Chisel	EU-HA-40
41	Plier for Orthodontics	EU-HA-41
42	Hollow Ware Instrument	EU-HA-42





Blockchain ID

Signed on behalf of GGL Italy Branch:

L'Famoletti

Leonardo Pavoletti General Manager E. F.

Eduardo Ricagni Scheme Manager

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