



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.

Certificate Holder	Hand Automation Surgical
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
Assessment Route	EC Declaration of Conformity (Annex IV of Regulation (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 Parliament 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 lose its validity automatically.

Technical File Reference No.	CE-UK-2024-HA-84
Verification Report No.	CE2024.G.UK.90
Original Registration Date	February 14, 2024
Place, Date of Issue	Rome, February 14, 2024
Expiry Date of the Certificate	February 13, 2025



CE-UK-2024143



Signed on behalf of GGL Italy Branch:

Leonardo Pavoletti
General Manager

Eduardo Ricagni
Scheme Manager



Blockchain ID

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)

Italy office: Via di Campo Marzio, 634, 00186 Rome RM, Italy
Web: www.gitchiagroup.com | E-mail: info@gitchiagroup.com

証明書

الشهادات

Certifikat

Zertifikat

Certificado

Довідка

Certificat

Sertifikat

Certificate

Сертифікат



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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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Signed on behalf of GGL Italy Branch:

L. Pavoletti

Leonardo Pavoletti
General Manager

E. Ricagni

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Scheme Manager



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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



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