



Certificate

No. Q5 104485 0004 Rev. 02

Holder of Certificate: **GA Health Company Limited**

Unit 18, 21/F, Metropole Square
2 On Yiu Street
Shatin, N.T.
HONG KONG

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Disposable Podiatry Set, Disposable Tourniquet, Forceps, Scissors, Needle Holder/Clamp, Speculum, Hook/Chopper, Punch, Marker/Caliper, Fixation Ring, Peeler, Lasek Alcohol Well, Retractor, Curette, Dilator, Depressor, Lasik Cannula (Single Hole at Tip), Irrigation Aspiration Cannula, Vitreo-Retinal Instrument, Ophthalmic Surgical Customized Pack, IV Bag Safety Connector, Trimano Application-Dressing Tray Pack, Disposable Biopsy Valve, Disposable Endoscope Bite Block and Disposable Endoscope Valves Set(Air/Water Valve, Suction Valve and Biopsy Valve), Single Use Suction Tubes, Disposable Suction Cannulas, Single Use Elastic Stay Retractor and Disposable Endoscope Polyp Trap, Disposable Auxiliary Water Connector, Air/water Tubing Set, CO2 Source Tubing with Luer Input, Endoscope Cleaning Brushes, Eye Pads

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:Q5 104485 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_104485_0004_Rev.02)

Report No.: SH2040703

Valid from: 2021-03-01
Valid until: 2024-02-28

Date, 2021-02-26



Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): GA Health Company Limited
Unit 18, 21/F, Metropole Square, 2 On Yiu Street, Shatin, N.T.,
HONG KONG

Design and Development, Production and Distribution of
Disposable Podiatry Set, Disposable Tourniquet, Forceps,
Scissors, Needle Holder/Clamp, Speculum, Hook/Chopper, Punch,
Marker/Caliper, Fixation Ring, Peeler, Lasek Alcohol Well,
Retractor, Curette, Dilator, Depressor, Lasik Cannula (Single Hole
at Tip), Irrigation Aspiration Cannula, Vitreo-Retinal Instrument,
Ophthalmic Surgical Customized Pack, IV Bag Safety Connector,
Trimano Application-Dressing Tray Pack, Disposable Biopsy
Valve, Disposable Endoscope Bite Block and Disposable
Endoscope Valves Set(Air/Water Valve, Suction Valve and Biopsy
Valve), Single Use Suction Tubes, Disposable Suction Cannulas,
Single Use Elastic Stay Retractor and Disposable Endoscope
Polyp Trap, Disposable Auxiliary Water Connector, Air/water
Tubing Set, CO2 Source Tubing with Luer Input, Endoscope
Cleaning Brushes, Eye Pads

GA Health Company Limited
F3, 9 Fuzhong Road, GuanTian District, Longjiang, Shunde,
528318 Foshan, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Production of
Endoscope Cleaning Brushes, Eye Pads, Biopsy Valve (Non-
sterile), Bite Block (Non-sterile), Polyp Trap, Tourniquets

Smartdata Suzhou Co., LTD
F4, Building 7, 198 Jinshan Road, 215011 Suzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA

Production of Disposable Podiatry Set, Disposable Tourniquet,
Forceps, Scissors, Needle Holder/Clamp, Speculum,
Hook/Chopper, Punch, Marker/Caliper, Fixation Ring, Peeler,
Lasek Alcohol Well, Retractor, Curette, Dilator, Depressor, Lasik
Cannula (Single Hole at Tip), Irrigation Aspiration Cannula, Vitreo-
Retinal Instrument, Ophthalmic Surgical Customized Pack, IV Bag
Safety Connector, Trimano Application-Dressing Tray Pack,
Disposable Biopsy Valve, Disposable Endoscope Bite Block and
Disposable Endoscope Valves Set(Air/Water Valve, Suction Valve
and Biopsy Valve), Single Use Suction Tubes, Disposable Suction
Cannulas, Single Use Elastic Stay Retractor and Disposable
Endoscope Polyp Trap, Disposable Auxiliary Water Connector,
Air/water Tubing Set, CO2 Source Tubing with Luer Input