

# EC Declaration of Conformity

We herewith declare that the under-mentioned products are in conformity with the general safety and performance requirements and provisions of Regulation (EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer. This declaration of conformity is issued under the sole responsibility of SAEHAN CORPORATION.

**Product Group :** Hand Evaluation Equipment

**Product Name:** ※ Details refer to Annex

**Model Name:** ※ Details refer to Annex

**Basic UDI-DI:** ※ Details refer to Annex

**SRN :** KR-MF-000024141

**Classification:** Class I (Regulation (EU) 2017/745 on medical devices Annex VIII Rule 1 is Class I)

**Conformity Assessment Route :** Annex IX, Regulation (EU) 2017/745 on medical devices

**Applied Standard:** EN ISO14971:2019, ISO/TR 24971:2020, EN 62366-1:2015+A1:2020, EN ISO 15223-1:2016, EN 1041:2008 /A1:2013, MEDDEV 2.7/1 [Rev. 4], MEDDEV 2.12/1 [Rev. 8], MEDDEV 2.12/2 [Rev. 2]

**Manufacture:** SAEHAN CORPORATION

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**EC Representative:** MVS In Motion

Westdijk 150 2830 Tiselt Belgium

SRN : BE-AR-000000661

**GMDN Code No.:** ※ Details refer to Annex

**EC Certificate :** SH-DOC-001



Signature:

A handwritten signature in blue ink, appearing to read 'G. J. Jeon', is written over a yellow rectangular background.

**Place of Issue:** Changwon-si, Gyeongsangnam-do, Korea

**Date of Issue:** 6 Feb, 2023

**G. J. Jeon / CEO**

[Annex]

REF	Description	BUDI-DI	UDI-DI
SH5001	Hydraulic Hand Dynamometer, hard case	880951372S1YR	8809513720038
SH5002	Spring Hand Dynamometer, soft case	880951372S1YR	8809513720076
SH5005	Hydraulic Pinch Gauge, hard case	880951372S1YR	8809513720045
SH5005-1	SAEHAN Mechanical Pinch Gauge, soft case	880951372S1YR	8809513720359
SH5007	Back-Leg-Chest Dynamometer	880951372S1YR	8809513720380
SH5008	Squeeze Dynamometer, soft case	880951372S1YR	8809513720052
SH5020	Skinfold Caliper, soft case	880951372S2YT	8809513720069
SH5100	Finger Goniometer, 14cm(5.5")(St. Steel)	880951372S3YV	8809513720090
SH5101	Finger Goniometer, 9cm(3.5")(St. Steel)	880951372S3YV	8809513720106
SH5102	Pocket Goniometer, 18cm(7")long, 180degree(St. Steel)	880951372S3YV	8809513720113
SH5103	Goniometer, 19cm(7.5")long, 180degree(St. Steel)	880951372S3YV	8809513720120
SH5104	Goniometer, 36 cm(14") long, 180 degree(St. Steel)	880951372S3YV	8809513720137
SH5105	Goniometer, 36 cm(14") long, 360 degree(St. Steel)	880951372S3YV	8809513720144
SH5106	X-Ray Goniometer, 20 cm(8") long, 180 degree(Aluminum)	880951372S3YV	8809513720151
SH5110	6 pcs Goniometer Set, soft case(St. steel+Aluminum) (SH5100+SH5102+SH5103+SH5104+SH5105+SH5106)	880951372S3YV	8809513720021
SH5200	17 cm(6.7") long, Pocket goniometer, 180 degree(Plastic)	880951372S3YV	8809513720168
SH5201	15.8 cm(6.2") long, 1.0mm thickness, goniometer, 360 degree(Plastic)	880951372S3YV	8809513720175
SH5202	20.5 cm(8.1") long, 1.0mm thickness, goniometer, 360 degree(Plastic)	880951372S3YV	8809513720182
SH5203	31.5 cm(12.4") long goniometer, 360 degree(Plastic)	880951372S3YV	8809513720199
SH5204	Flexion/Hyper-Extension goniometer(Plastic)	880951372S3YV	8809513720205
SH5205	22 cm(8.7") long, 0.8mm thickness, Rulong goniometer, 360 degree(Plastic)	880951372S3YV	8809513720212
SH5205-1	22 cm(8.7") long, 2.0mm thickness, Rulong goniometer, 360 degree(Plastic)	880951372S3YV	8809513720229
SH5206	6 pcs Goniometer Set, soft case(Plastic) (SH5200+SH5201+SH5202+SH5203+SH5204+SH5205)	880951372S3YV	8809513720083
SH5208	Multi-Finger Flexion Goniometer(Plastic)	880951372S3YV	8809513720311
SH5114	Wartenberg Pinwheel	880951372S4YX	8809513720489
SH5000-3	Hand Evaluation Kit, 3pcs, hard case (SH5001+SH5005+SH5100)	880951372S5YZ	8809513720328
SH5000-3M	Hand Evaluation Kit, 3pcs, hard case (SH5001+SH5005-1+SH5100)	880951372S5YZ	8809513720496
SH5000-7	Hand Evaluation Kit, 7pcs, hard case (SH5001+SH5005+SH5100+SH5025+SH5023-1+SH5028 +SH5114)	880951372S5YZ	8809513720304

## I. Product Name & Model Name

No.	Product Name	Model Name
1	Hydraulic Hand Dynamometer	SH5001
2	Spring Hand Dynamometer	SH5002
3	Back-Leg-Chest Dynamometer	SH5007
4	Squeeze Dynamometer	SH5008
5	Hydraulic Pinch Gauge	SH5005
6	Mechanical Pinch Gauge	SH5005-1
7	Skinfold Caliper	SH5020
8	Stainless Steel & Aluminum Goniometer	SH5100 & SH5101 & SH5102 & SH5103 & SH5104 & SH5105 & SH5106 & SH5110
9	Plastic Goniometer	SH5200 & SH5201 & SH5202 & SH5203 & SH5204 & SH5205 & SH5205-1 & SH5206 & SH5208
10	Wartenberg Pinwheel	SH5114
11	Hand Evaluation Kit <sup>(*)</sup>	SH5000-3 & SH5000-7 & SH5000-3M

## II. GMDN Code

[Hydraulic Hand Dynamometer & Hydraulic/Mechanical Pinch Gauge]  
: 35021 (Dynamometer, Hand)

[Spring Hand Dynamometer]  
: 35021 (Dynamometer, Hand)

[Back-Leg-Chest Dynamometer]  
: 34395 (Dynamometer, Back)

[Squeeze Dynamometer]  
: 11367 (Dynamometer, Squeeze)

[Skinfold Caliper]  
: 34890 (Caliper, Skinfold, Manually-operated)

[Stainless Steel&Aluminum/Plastic Goniometer]  
: 11893 (Goniometer)