

# HEINE Classic+ Laryngoscope Blades



DATA							
Description	Mac 0	Mac 1	Mac 2	Mac 3	Mac 3m	Mac 4	Mac 5
Catalogue number	F.000.22.100	F.000.22.101	F.000.22.102	F.000.22.103	F.000.22.143	F.000.22.104	F.000.22.105
Date	March 11, 2021						

MECHANICAL							
Weight product	typ. 67 g	typ. 75 g	typ. 109 g	typ. 121 g	typ. 124 g	typ. 139 g	typ. 171 g
Weight packing including product	typ. 80 g	typ. 90 g	typ. 125 g	typ. 135 g	typ. 145 g	typ. 160 g	typ. 190 g
Blade length according to ISO 7376	66 mm	78 mm	98 mm	118 mm	118 mm	139 mm	161 mm
Blade length	82 mm	94 mm	114 mm	134 mm	134 mm	155 mm	177 mm
Blade proximal width	23 mm	23 mm	28 mm	28 mm	28 mm	28 mm	28 mm
Blade distal width	9 mm	10 mm	14 mm	14 mm	14 mm	15 mm	15 mm
Blade height	24 mm	27 mm	31 mm	30 mm	32 mm	31 mm	31 mm
Dimensions packing	43 x 27 x 117 mm	43 x 27 x 117 mm	43 x 27 x 117 mm	49 x 28 x 163 mm	49 x 28 x 163 mm	49 x 28 x 163 mm	52 x 28 x 216 mm
Connections	hook-on system for laryngoscope handle (according to ISO 7376)						
Imprints	HEINE MADE IN GERMANY, logo, symbols, product name, product number, blade size, CE, MD, ISO 7376, manufacturing year, stainless steel, serial number, www.heine.com, data matrix code						

CODES							
Customs code (tariff number)	90189084						
GTIN	4053755127436	4053755127481	4053755127542	4053755127603	4053755128051	4053755127672	4053755127740
Country of origin	DE						



DATA						
Description	Miller 00	Miller 0	Miller 1	Miller 2	Miller 3	Miller 4
Catalogue number	F.000.22.119	F.000.22.120	F.000.22.121	F.000.22.122	F.000.22.123	F.000.22.124
Date	March 11, 2021					

MECHANICAL						
Weight product	typ. 51 g	typ. 52 g	typ. 62 g	typ. 84 g	typ. 104 g	typ. 111 g
Weight packing including product	typ. 65 g	typ. 70 g	typ. 75 g	typ. 100 g	typ. 115 g	typ. 125 g
Blade length according to ISO 7376	51 mm	55 mm	78 mm	130 mm	170 mm	185 mm
Blade length	76 mm	80 mm	100 mm	152 mm	192 mm	207 mm
Blade proximal width	20 mm	18 mm	18 mm	23 mm	23 mm	25 mm
Blade distal width	10 mm	11 mm	12 mm	13 mm	13 mm	16 mm
Blade height	24 mm	21 mm	23 mm	23 mm	22 mm	22 mm
Dimensions packing	43 x 27 x 117 mm	43 x 27 x 117 mm	43 x 27 x 117 mm	49 x 28 x 163 mm	52 x 28 x 216 mm	52 x 28 x 216 mm
Connections	hook-on system for laryngoscope handle (according to ISO 7376)					
Imprints	HEINE MADE IN GERMANY, logo, symbols, product name, product number, blade size, CE, MD, ISO 7376, manufacturing year, stainless steel, serial number, www.heine.com, data matrix code					

CODES						
Customs code (tariff number)	90189084					
GTIN	4053755127832	4053755127863	4053755127894	4053755127924	4053755127955	4053755127986
Country of origin	DE					



DATA					
Description	Paed 0	Paed 1	WIS 1	WIS 2	WIS 3
Catalogue number	F-000.22.110	F-000.22.111	F-000.22.131	F-000.22.132	F-000.22.133
Date	March 11, 2021				

MECHANICAL					
Weight product	typ. 72 g	typ. 75 g	typ. 62 g	typ. 83 g	typ. 96 g
Weight packing including product	typ. 85 g	typ. 90 g	typ. 80 g	typ. 100 g	typ. 115 g
Blade length according to ISO 7376	65 mm	78 mm	85 mm	105 mm	133 mm
Blade length	82 mm	95 mm	110 mm	130 mm	160 mm
Blade proximal width	23 mm	23 mm	20 mm	22 mm	22 mm
Blade distal width	12 mm	13 mm	13 mm	16 mm	16 mm
Blade height	27 mm	27 mm	29 mm	32 mm	32 mm
Dimensions packing	43 x 27 x 117 mm	43 x 27 x 117 mm	43 x 27 x 117 mm	49 x 28 x 163 mm	49 x 28 x 163 mm
Connections	hook-on system for laryngoscope handle (according to ISO 7376)				
Imprints	HEINE MADE IN GERMANY, logo, symbols, product name, product number, blade size, CE, MD, ISO 7376, manufacturing year, stainless steel, serial number, www.heine.com, data matrix code				

CODES					
Customs code (tariff number)	90189084				
GTIN	4053755127771	4053755127801	4053755128013	4053755128037	4053755128044
Country of origin	DE				



<b>OPTICAL</b>	
Type	fiberglass optic
Luminous flux*	typ. 9 lm
Illuminance*	typ. 7000 lx

<b>GENERAL</b>	
Material	stainless steel
REACH/RoHS	conform
Phthalate	contains no phthalate
Latex	contains no latex
Biocompatibility	conform
Surface	chrome
Environmental conditions operation	temperature: +10 °C to +35 °C, relative humidity: 30 % to 80 %, air pressure: 700 hPa to 1060 hPa
Environmental conditions storage	temperature: -40 °C to +70 °C, relative humidity: up to 95 % (n.c.), air pressure: 500 hPa to 1060 hPa
Environmental conditions transport	temperature: -40 °C to +70 °C, relative humidity: up to 95 % (n.c.), air pressure: 500 hPa to 1060 hPa
Instructions for use **	Deutsch, English, Francais, Espanol, Italiano, Svenska, Nederlands, Dansk, Norsk, Suomi, Portugues
Operating elements	none
Removable parts/ accessories	laryngoscope handle
Maintenance	the device is maintenance-free
Service	the device is service-free
Guarantee	Guarantee of 10 years since delivery date 01.01.2020 (serial number > SN1105230000)
Patents	n/a

<b>HYGIENIC REPROCESSING</b>	
Procedure	please see detailed description in the reprocessing procedure

<b>REGULATORY</b>	
Product classification (EU)	class I
Product classification (USA)	class 1, 510(k) exempt
Product classification (Canada)	class II
UMDNS code	15-076
GMDNS code	46827
Regulation number (FDA)	868.5540
Product code (FDA)	CCW

<b>FULFILLS THE REQUIREMENTS OF DIRECTIVES &amp; STANDARDS</b>	
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
Directive 93/42/EEC	Concerning medical devices
DIN EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
DIN EN ISO 7376	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
DIN EN 60601-1	Medical electrical equipment: General requirements for basic safety and essential performance
IEC 60601-2-18	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
DIN EN 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
ISO 14971	Medical devices - Application of risk management to medical devices
DIN EN 60601-1-12	Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
DIN EN 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential
DIN EN 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
DIN EN 62471	Photobiological safety of lamps and lamp systems
IEC 60601-1-9	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential
ISO 17664	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 2248	Packaging: complete, filled transport packages; vertical impact test by dropping
Directive (2011/65/EU) ROHS	On the restriction of the use of certain hazardous substances in electrical and electronic equipment
Directive (2012/19/EU) WEEE	On Waste Electrical and Electronic Equipment
Regulation (1907/2006) REACH	Registration, Evaluation, Authorization and Restriction of Chemicals

\*) measured with HEINE EasyClean LED laryngoscope handle and size 3 blade

\*\*) further languages on request

