

Declaration of Conformity

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of Medical Devices Regulation (EU) 2017/745 and RoHS Directive 2011/65/EU.

Product Category:	Measuring and Monitoring Device for Vital Signs
Device Name:	Reusable Accessories for DS-8100 (Multi-Parameter Patient Bedside Monitors) *See Appendix 1 for the complete list.
Classification:	Class I (self-certified) Rule 1, Annex VIII of Medical Devices Regulation (EU) 2017/745
Basic UDI-DI:	4538612020009M
Intended Purpose:	These are accessories to support DS-8100 or use to operate DS-8100. This device intends to measure the vital signs to monitor patient condition by displaying and printing the measurement data on this device or central monitor and to generate alarm when necessary. The vital signs are electrocardiogram, heart rate, respiration rate, body temperature, arterial oxygen saturation (SpO ₂), pulse rate, invasive blood pressure, non-invasive blood pressure, CO ₂ concentration, cardiac output (CO) and blood temperature.
EEE Categories:	8 Annex I of RoHS Directive 2011/65/EU
Manufacturer:	Fukuda Denshi Co., Ltd. 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
SRN:	JP-MF-000008253
European Authorized Representative:	Emergo Europe Prinsessegracht 20, 2514 AP The Hague, The Netherlands
SRN:	NL-AR-000000116
Technical Documents:	No. 063150H-24203

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of RE Directive 2014/53/EU.

Product Category: Measuring and Monitoring Device for Vital Signs
Device Name: TM XMTR Module HLX-801
Model: HLX-801
Type: HLX-801
Manufacturer: Fukuda Denshi Co., Ltd.
3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Location of design: Fukuda Denshi Co., Ltd. Hongo Office
2-35-8 Hongo, Bunkyo-ku, Tokyo, Japan
Location of production: Fukuda Denshi Co., Ltd. Shiroy Factory
305-1 Naka, Shiroy-shi, Chiba, Japan
Applied Annex: Annex II of Directive 2014/53/EU
Technical file: No. 063020D-17614

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Appendix 1.

Reusable Accessories for DS-8100 (Multi-Parameter Patient Bedside Monitors) intended to be used in combination with DYNASCOPE 8000 Series DS-8100 System.

Device Name	Type
HCP Attachment Case for DS-8100	OAO-65A
Stand for DS-8100	OAO-66A
Rail/Pole Clamp for DS-8100 (VESA75mm)	OAO-84A
Bed Mount for DS-8100 (VESA75mm)	OAO-85A
HCP Fixing Bracket for DS-8100	OAO-86A
Counter Bracket (for OAO-66A)	OAO-87A
Clip Bracket for DS-8100	OAO-90A
Recording paper	OP050-02TDR
TM XMTR Module HLX-801	HLX-801
Lithium-ion Battery Pack	BTO-008
IR Remote Control Unit	CF-820
CF Card	FCF-128
	FCF-1000
	FCF-16GA
SD Card	SD-1G
	SD-8G
Module Connection Cable	CJO-13SS1.5
	CJO-13SS3.5
	CJO-13SS5
Network Cable	CJO-14SS1.5
	CJO-14SS2.5
	CJO-14SS5
	CJO-14SS10
	CJO-14SS20
AUX Connection Cable	CJO-15RR0.17
	CJO-15RR0.65
	CJO-15RR1.5
	CJO-15RR3
Potential equalization cord	CE-11
Earth wire	CE-01A
Ethernet Branch Cable	CJ-522A
	CJ-522B
	CJ-522C
	CJ-522D
	CJ-522E
BIS Monitor interface cable	CJO-03RS4
RS-232C Cross cable	CJ-725
SV-300 interface cable	CJ-401RI-70SV3
Relay Cable	CJ-402RI-70SVi
PB700/800 serial interface cable	CJ-403RI-70PB
BIS Monitor interface cable	CJ-407RI-70BIS
Serial Converter Cable	CJ-756
Power Cable	CS-18
	CS-55-ST
	CS-55-RA

Device Name	Type
	CS-56-ST
	CS-57-ST
	CS-57-RA
	CS-58-ST
	CS-59-ST
Trolley(S)	OTO-16S
Detachable Attachment for Patient Monitor	OA0-1000
Mounting Bracket for DS-8100	OA0-1001A

ECG Accessory

Device Name	Type
ECG Relay Cable	CIO-05CTP-3NU
	CIO-05CTP-4NU
	CIO-05CTP-5NU
ECG Relay Cable	CIO-08CTP-3EU
	CIO-08CTP-5EU
Patient Cable Adapter	CIZ-173DIN-3-U
	CIZ-173DIN-5-U

Blood Pressure Accessory

Device Name	Type
BP Relay Cable	CJO-P01B-SB3.6
2ch BP Relay Cable	CJO-P01B-DB0.8
	CJO-P01B-DB4.3
2ch BP Conversion Cable	CJO-P01B-DJ0.5

Temperature Accessory

Device Name	Type
2ch Temperature Relay Cable	CJO-P01T-DA0.5
	CJO-P01T-DA4.0

CO Accessory

Device Name	Type
Catheter Relay Cable	CJO-P01C-C2.4
Flow-Through Sensor Relay Cable	CJO-P01C-F2.4
In-Line Sensor Relay Cable	CJO-P01C-L2.4
Injectate Probe Relay Cable	CJO-P01C-T2.4

NIBP Accessory

Device Name	Type
Air Hose	OA-80APS1.5-S
	OA-80APS3.5-S
Air Hose	OA-80NE1.5-S
	OA-80NE3.5-S