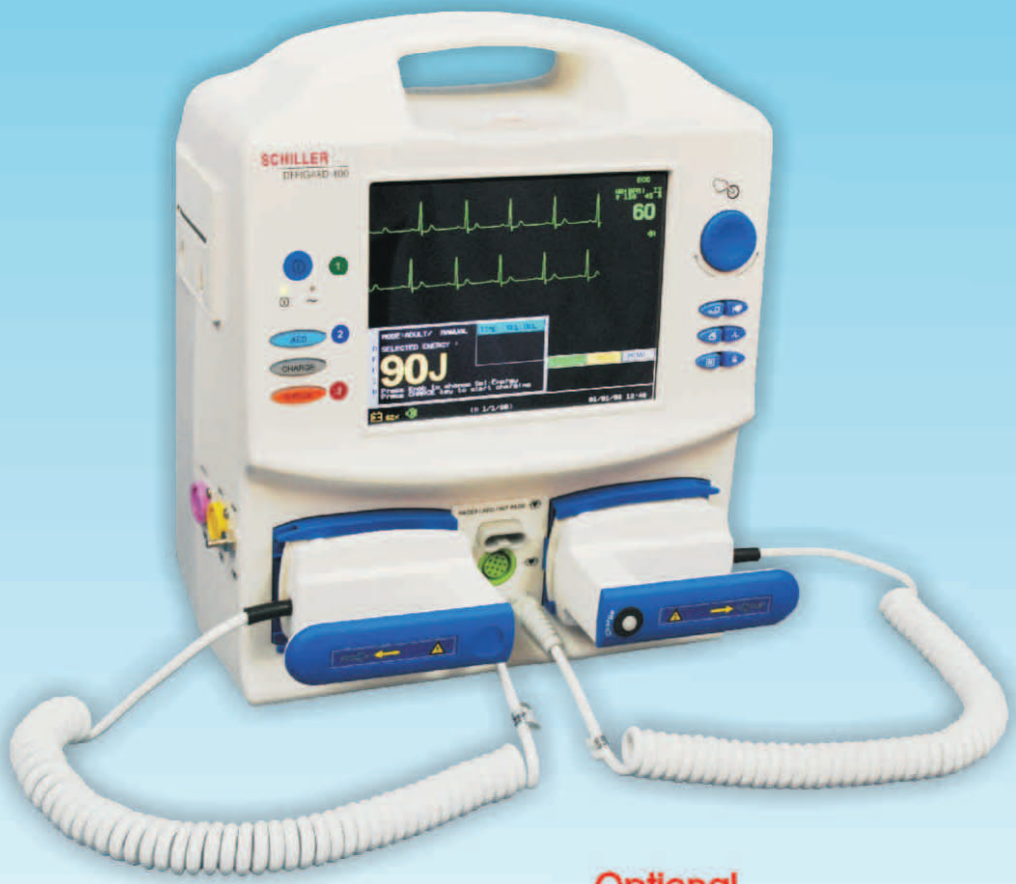
DEFIGARD® 400

Biphasic Defibrillator



Features

- Large 8.4" colour TFT screen with LED backlight
- Single rotary knob operation
- Direct function keys
- Visual instructions and guidance on screen
- 3 ECG strips memory
- 24 hours trend for all parameters
- Adult and pediatric application
- Light weight & portable

Optional

- 12 Lead ECG
- AED
- External pacemaker
- SpO_2
- NIBP
- $ETCO_2$
- Internal defibrillation
- Integrated thermal printer
- USB interface for data storage

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The Art of Diagnostics

DEFIGARD® 400 Technical Data

General

Net Wt : 7 to 8 kgs (Depending on Configuration)
Mains and battery operated
Power : 100-240 VAC, 50 Hz
Parameters displayed : Up to 2 ECG channels, HR, selected energy delivered energy, status bar, mains and battery charge, LED indicator
Other :
- Trim knob and direct function keys for Print, Mute & Freeze
- Auto Print on Alarm
- Digital out for Central Monitoring Station depending on the configuration
- 12 VDC Input
- 4 waveform display

Display

Size : 8.4"
Resolution : 800 x 600 pixels
Type : High resolution colour TFT with LED backlight

Trends

Memory : All parameters are stored for 24 hours
Format : Tabular and graphical
USB interface for data storage (optional): - Events and trend storage
- 1000 defib events with waveform
- 96 hours events of all parameters

Battery

Rechargeable, sealed lead acid battery (12V, 4.5 AH) or LI-Ion(optional)
Battery charging time :
Lead Acid : 10-12 hrs for a completely discharged battery
LI-Ion : 90 minutes to 80%
120 minutes for 100%
Unit operating time on Battery :
Lead Acid : 180 minutes in monitoring mode
LI-Ion : 210 minutes in monitoring mode
Mains & battery (%) charge indicator on display
Number of shocks on fully charged battery : ≥ 100 @ 200 J
: > 75 @ 360 J

Alarms

Graded alarms : Visual and acoustic
Alarm silence : 120 Seconds
Digital alarm volume control
System alarms : Monitor, defibrillator, battery charge
Physiological alarms : ECG, Tachycardia/ bradycardia

Defibrillator

For Manual Defibrillation
Energy levels :(User Selectable)
- Paddles : 1, 2, 4, 8, 15, 30, 50, 70, 90, 120, 150, 200 Optional : 250, 300 & 360 J
Reusable Adult & Paediatric Hard Paddles
Waveform : Impedance compensated biphasic
Charging time : 5 seconds for 200 J
Defibrillation mode : Non-synchronized, Synchronized, Manual, AED (optional)

Internal Defibrillation (optional)

Energy Selection: 2,4,8,15,30 & 50 J
Shock Delivery: Via Spoon Electrodes

ECG

Amplifier : Fully isolated, defibrillation - protected, >5 kv
Choice of leads : As per Selection
With 3 lead cable : Lead I, II, III, or
With 5 lead cable : Lead I, II, III, aVR, aVL, aVF & V
With 10 lead cable (option) : Lead I, II, III, aVR, aVL, aVF, V_1, V_2, V_3, V_4, V_5, & V_6
Display trace : 4 sec single trace or 8 sec Dual trace ECG display
HR display : 30-300 bpm
Digital gain selection : 2.5, 5, 10, 20 mm/mv
ECG strip selection for storage & printing
Sampling frequency : 240 Hz
Inputs : CF class patient cable 5 leads
User selectable baseline
Freeze ECG
Alarm Limits:
HR low limit - 1 to 115 bpm
HR Hi limit - 120 to 300 bpm

Automated External Defibrillator (optional)

Voice and visual prompts to guide the user
Energy delivered through adult or child pads

Mode	: Adult / Child
Adult AED	130 / 150 / 200 Joules
Child AED	15 / 30 / 50 Joules
Shock Delivery	Via Pads

Automatic detection of Adult / Child pad

External Pacemaker (optional)

Transcutaneous Pacer
Operating mode: Fix, demand and overdrive (frequency *3)
Duration: 40 ms (20 ms in over drive mode) ± 10%
Frequency: 40 to 210 p/min ± 5%
Pace output current : 35 to 150 MA ± 5%

Pulse Oximetry (Optional)

Optional: Nellcor/ Digital
Amplifier: Fully isolated, defibrillation - protected > 5 kv
Display:
- Numerical display in %
- Graphic display of signal strength
- Plethysmogram
- Numerical display of the peripheral pulse rate
- Text error messages
Pulse range: 0 to 300 bpm
Accuracy:
- Adult: 70 to 100% (+ 2 digits)
50 to 69% (+ 3 digits)
- Neonatal: 70 to 100% (+ 3 digits)
0 to 49% (unspecified)
Alarm Limit:
Low limit - 5 to 95 %
HI limit - 10 to 100 %

NIBP (optional)

Measuring principle: Oscillometric
Measuring range: 10 to 270 mm/Hg
Accuracy : ± 5 mm Hg, Standard Deviation < 8 mmHg
Measurement: Automatic & manual mode
Display: Numerical, individual measurement values and trends
Alarm Limit:
Systolic Low limit - 10 to 145 mmHg
Systolic HI limit - 150 to 250 mmHg
Diastolic Low Limit - 10 to 115 mmHg
Diastolic HI limit - 120 to 250 mmHg

Thermal printer (optional)

Manual or Auto printout on defibrillator usage

Resolution	: High-resolution thermal printhead 8 dot/mm, 72 mm usable print width
Chart-Paper	: Thermo reactive,80 mm width, 'Z' folded, Approx. 200 Sheets
Print Speed	: 25 mm/s

Prints pre & post shock data, Trends

USB interface for data storage (optional)

Events and trend storage
2 GB data storage

Environmental conditions

Galvanic protection : CF type
Temperatures : +0° to + 50° C
Atmospheric pressure : 500 to 1060 hPa
Relative humidity : 15 to 95% (no condensation)

Options

$ETCO_2$

Accessories: (As per configuration)

- 5 Lead ECG cable - 1 no.
- Reusable ECG electrodes with stickers - 1 pack
- Earth cable - 1 no.
- Jelly bottle - 1 no.
- Power cord - 1 no.
- User manual - 1 no.
- Warranty card - 1 no.

Safety standards

IEC 60601
Conformity: CE 0123

Facility certification

ISO : 9001
ISO : 13485

J-1000-8/10-10

Accessories shown are not part of standard configuration. All registered trademarks acknowledged.

Technical data are subject to change without notice

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ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106331 0001 Rev. 00

Manufacturer:

Schiller Healthcare India Pvt. Ltd.
No.17, Pondy Villupuram Road, Balaji Nagar, Oulgaret
605010 Puducherry
INDIA

Product Category(ies): **Defibrillator, Patient monitor.**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: IND20190111

Valid from: 2020-03-20
Valid until: 2024-05-26

Date, 2020-03-20

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 106331 0001 Rev. 00

-/-

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Schiller Healthcare India Pvt. Ltd.
Plot No. 17, Pondy Villupuram Road
Balaji Nagar, Olugaret,
Puducherry - 605 010

Tel.: 0413-2291160 Fax: 0413-2292940
E-mail: mail@schillerindia.com
http://www.schillerindia.com

SCHILLER
INDIA

DECLARATION OF CONFORMITY WITH EEC DIRECTIVE 93/42

Ref: SCH/CE/006 dated: 01/01/2020

PRODUCT

Name : DEFIGARD 400
Function : Defibrillator with Monitor and Accessories
Classification : II b

Manufacturer

Manufacturers Site/Address:

SCHILLER Healthcare India Pvt Ltd
No. 17, Pondy Villupuram Road,
Balaji Nagar, Oulgaret,
Puducherry - 605 010

Person to be contacted:

Nandaraj Hosabettu: Vice President: R&D/Production/Quality Assurance & Regulatory Affairs.

Tel: 022 61523333

Authorized Representative in EU:

Schiller Medical SAS
4, rue Louis Pasteur
F67-162
Wissembourg
Cedex
France
Email : Alain WEISSINGER [alain.weissinger@schiller.fr]
Fax : +33 3 88 94 12 82

Schiller Healthcare India Pvt. Ltd.
Plot No. 17, Pondy Villupuram Road
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Tel.: 0413-2291160 Fax: 0413-2292940
E-mail: mail@schillerindia.com
http://www.schillerindia.com

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INDIA

Declaration

We, the undersigned, under sole responsibility, hereby declare that the medical device Defigard 400, specified above and with accessories specified in Annex A, conforms with the Directive 93/42/EEC.

CE labeling will be affixed in accordance with Article 17 of EEC directive 93/42.

All products are manufactured under full quality assurance system in accordance with Annex II – of directive 93/42/EEC, assessed by Notified Body TÜV SÜD Product Service GmbH vide Certificate Number **G1 106331 001 Rev 0.0**.

Notified Body

CE 0123

Notified Body Address:

TÜV SÜD Product Service GmbH, Ridlerstraße 65
80339 München

For Schiller Healthcare (I) Pvt Ltd

Nandaraj H

Vice President
Schiller Healthcare (I) Pvt. Ltd.

Nandaraj Hosabettu

Vice President (R&D/Production/Regulatory Affairs)

Validity from: 20th March 2020

Schiller Healthcare India Pvt. Ltd.
Plot No. 17, Pondy Villupuram Road
Balaji Nagar, Olugaret,
Puducherry - 605 010

Tel.: 0413-2291160 Fax: 0413-2292940
E-mail: mail@schillerindia.com
http://www.schillerindia.com

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Annex A

List of Accessories for Defigard 400

Part Number	Description
BECA010000	FUSE FAST BLOW 10A 5 X 20MM
N00300MC4S	MAINS CABLE WITH PLUG 3 PIN
NMNDG40020	USER MANUAL FOR DG400
VDSMLGLT01	DISPOSABLE ELECTRODE
VJLY100SPN	ECG JELLY 100ml
VPCECGSAML	5 LEAD ECG CABLE 12 PIN FOR DG400
VSTINSHEET	INSTALLATION INSTRUCTION SHEET
VPCDGECG12	12 LEAD ECG PATIENT CABLE FOR DG400
SUBASYEARDG4	DG400 - EARTH CABLE ASSY
VDG40ELECT	DEFIBRILLATION PACING ELECTRODES - ADULT
VDG4PDELCT	DEFIBRILLATION PACING ELECTRODES PEDIATRIC
NCP8090200	CHART PAPER {80mm X 90 mm X 200 SHEETS}
VADUCUFBLT	ADULT CUFF WITH CONNECTOR
VEXTNUBBLT	EXTENSION TUBE FOR BP CUFF
VNE0CUFBLT	NEONATAL CUFF WITH CONNECTOR
VPEDCUFBLT	PEDIATRIC CUFF WITH CONNECTOR
A1CHN9SSAM	ADULT FINGER SP02 PROBE (9PIN)
50.000125L	DIGITAL Y SENSOR
VPCSP2CHSM	12PIN DIGITAL SP02 PROBE EXTENSION CABLE
A1PENDRIVE	USB FLASH DRIVE 4GB/8GB/16GB (PEN DRIVE PRINTED)
VCDC0VER00	CD COVER
VCDS0FTWER	SOFTWARE CD 700MB/80 MIN CD-R 52x
200101S	ETCO2 MAIN STREAM - MASIMO
VPCETC02CG	ETCO2 EXTN.CABLE FOR CAPNOGRAM

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TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 041505 0120 Rev. 00

Manufacturer:

SCHILLER AG
Altgasse 68
6341 Baar
SWITZERLAND

Facility(ies):

SCHILLER Engineering Austria GmbH
Defreggergasse 5, 8020 Graz, AUSTRIA

SCHILLER AG
Altgasse 68, 6341 Baar, SWITZERLAND

Product Category(ies):

Electrocardiographs, ECG Holters, ECG Analysis Software, Spirometers, Sphygmomanometers, Monitoring Devices, Monitoring Systems, Central Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation Devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713154696

Valid from: 2019-04-17
Valid until: 2024-04-16

Date, 2019-04-17

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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KVQA

Certificate of Registration

(Quality Management System)

KVQA CERTIFICATION SERVICES PVT. LTD.

This is to certify that the Quality Management System of

SCHILLER HEALTHCARE INDIA PVT. LTD.

UNIT I : NO.17, PONDY-VILLUPURAM ROAD, BALAJI NAGAR, OULGARET, PUDUCHERRY – 605 010, INDIA

UNIT II : NO.15/5 & 15/6, VAZHUTHAVUR ROAD, KURUMBAPET, PUDUCHERRY – 605 009, INDIA

Has been found to be of the Quality Management System Standard

ISO 9001:2015

This certificate is valid for the following product or service range

DESIGN, MANUFACTURE, INSTALLATION & SERVICING OF PATIENT MONITORING SYSTEMS, RESTING ECG / STRESS ECG SYSTEMS, TREADMILL, DEFIBRILLATORS, VENTILATORS AND ACCESSORIES

Certificate No: IQSC202011013

1st Surveillance Due On: 26/10/2021: Done On:
2nd Surveillance Due On: 26/10/2022: Done On:

Date Of Issue: 26, November, 2020
Valid Until: 25, November, 2023*

IAF

Issued by

Authorised signatory KVQA

JAS-ANZ

M5400913IN

www.jas-anz.org

JAS-ANZ is the government-appointed accreditation body for Australia and New Zealand responsible for providing accreditation of conformity assessment bodies (CABs) in the fields of certification and inspection. Accreditation by JAS-ANZ demonstrates the competence and independence of KVQA.

Accredited by a member of IAF's MLA for Quality Systems

To Check the Status of the Certification kindly log on to www.kvqa.in
F-300, Sector -63, Noida U.P., India. Ph-011-22711940, 22711941, email: delhi@kvqaindia.com
*Subject to successful completion of surveillance audits

Schiller Healthcare India Pvt. Ltd. New Delhi

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America

CERTIFICATE

No. QS6 18 06 41505 114

Certificate Holder: SCHILLER AG
Altgasse 68
6341 Baar
SWITZERLAND

Certification Mark:

Scope of Certificate: Design and Development, Production, Service and Distribution of Electrocardiographs and Thermal Paper as accessory, Sphygmomanometers, Spirometers, Monitoring Devices, Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation Devices

Standard(s): ISO 13485:2016

Regulatory Authority: Australia TGA, Brazil ANVISA, Health Canada, USA FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 48-086-8538
Effective Date: 2018-06-26
Expiry Date: 2021-06-25

Manuel Bradaric
MHS Certification Manager

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America

CERTIFICATE

No. QS6 18 06 41505 114

SCHILLER AG
Altgasse 68
6341 Baar
SWITZERLAND
DUNS No: 48-086-8538

Design and Development, Production, Service and Distribution of Electrocardiographs and Thermal Paper as accessory, Sphygmomanometers, Spirometers, Monitoring Devices, Monitoring Systems, Cardiopulmonary Exercise Testing Systems, Defibrillators, Telemetry Devices and Cardiopulmonary Resuscitation Devices

SCHILLER Engineering Austria GmbH
Defreggergasse 5
8020 Graz
AUSTRIA
DUNS No: 30-045-4134

Design and Development of Monitoring Devices, Monitoring Systems

Effective Date:	**2018-06-26**
Expiry Date:	**2021-06-25**

Manuel Bradaric
Certification Manager MHS

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UCB_F_12.02 2012-02

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America

CERTIFICATE

No. QS6 18 06 41505 114

Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Effective Date: 2018-06-26
Expiry Date: 2021-06-25

Manuel Bradaric
Certification Manager MHS

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UCB_F_12.02 2012-02

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 106331 0002 Rev. 00

Holder of Certificate: **Schiller Healthcare India Pvt. Ltd.**
No.17, Pondy Villupuram Road, Balaji Nagar, Oulgaret
605010 Puducherry
INDIA

Facility(ies):
Schiller Healthcare India Pvt. Ltd.
No.17, Pondy Villupuram Road, Balaji Nagar, Oulgaret, 605010 Puducherry, INDIA

Certification Mark:

Scope of Certificate: **Design and development, Production, Installation and service of Patient Monitoring Systems, Resting ECG, Stress ECG, Defibrillator and Accessories**

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

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). See also notes overleaf.

Report No.: IND20190111

Valid from: 2020-03-20
Valid until: 2023-03-19

Date, 2020-03-20

Christoph Dicks
Head of Certification/Notified Body

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