

DIGNITANA

DECLARATION OF CONFORMITY

Product Identification:

Product Name	Part Number
DigniCap Delta® Scalp Cooling System (One single Delta unit with an English IFU - w/o accessories or cord kit)	900-1001

(See schedule A for additional part numbers)

Brand Name: DigniCap Delta®

Manufacturer:

Name: Dignitana, AB – CE certificate # G1 037539 0010 Rev. 01
Address: Traktorgränden 3
226 60 Lund
Country: Sweden

Notified Body:

Name: TÜV SÜD Product Service GmbH, Zertifizierstelle (ID #0123)
Address: Ridlerstraße 65, 80339 München, Germany
Phone: +49 (0)89 5791-0

Authorized Representative in Europe:

Name: Dignitana, AB
Address: Traktorgränden 3,
226 60 Lund
Country: Sweden

We, the manufacturer – with sole responsibility, hereby declare that the below mentioned products comply with the essential requirements and provisions of Council Directive 93/42/EEC for Medical Devices, the Directive 2007/47/EC and its relevant transposition into national laws of the member states into which we place the devices.

Device Classification is IIa per rule 9.

Route to Compliance is MDD Annex II.3

Signature:

Place: Lund, Sweden

Date:

September 1st 2023 / 2023-09-01

Signature:

Catarina Löwenadler

Name: Catarina Mård Löwenadler,
Chief Executive Officer

DIGNITANA

System Name: DigniCap Delta® Scalp Cooling System

Schedule A

DigniCap Delta® Unit

Part Number	Description
900-1001	System, DigniCap Delta Scalp Cooling, DCD-01
900-1002	Aurora Bio Science Distributor Package
900-1003	MedPhy India Distributor Package
900-1004	KM Japan Distributor Package
900-1005	RBK Korea Distributor Package

Connection Kits

900-2001	Kit, Connection, US, DCD-01
900-2002	Kit, Connection, EU, DCD-01
900-2003	Kit, Connection, UK, DCD-01
900-2004	Kit, Connection, AU, DCD-01

Delta Cards

800-1101	1-ct Single-Use Global DeltaCard, DCD
800-1001	25-ct box of Single-Use Delta Cards
800-1125	1-ct Multi-Use DeltaCard- (25 Treatments per Card)
800-1025	25-ct box of Multi-Use Delta Cards (25 Treatments per Card in a 25-ct box) 625 treatments

Delta Cool

800-1203	Delta Cool, DCD, 5 pk International (Case of 5, 1-Litre bottles) [bottled in Lund]
800-1202	Delta Cool, DCD, 6 pk, International (Case of 6, 500mL bottles) [bottled in US]
800-1201	Delta Cool, DCD, 10 pk Domestic (case of 10)

Delta Kits (for patient use)

800-2001	Delta Kit 1 (Mesh bag includes Cooling Wrap, Thermal, Chin Strap, Wet Brush, Spray Bottle, Headband, & Patient Guide)
800-2002	Delta Kit 2 (Mesh bag includes Cooling Wrap, Chin Strap, Wet Brush, Spray Bottle, Headband, & Patient Guide)
800-2003	Delta Kit 3 (Mesh bag includes Cooling Wrap, Chin Strap, Headband, & Patient Guide)

Ans

Traktorgränden 3, 226 60 Lund, Sweden
10925 Estate Lane W-185, Dallas, TX 75238 USA

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dignicap.com

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A la carte orderable items

Part Number	Description
800-1102	1-ct Cooling Wrap, Head, Med (Standard size), Dripless, SPU
800-1002	Cooling Wrap, Head, Med (Standard size), Dripless, SPU/case of 10
800-1103	1-ct Cooling Wrap, Head, Small, Dripless, SPU
800-1003	Cooling Wrap, Head, Small, Dripless, SPU/ case of 1
800-1104	1-ct Outer Blue Thermal Cap, UNIV, SPU, DCD-01
800-1004	Outer Blue Thermal Cap, UNIV, SPU, DCD-01/ case of 10
800-1005	1-ct Chin Strap, Single
600-1001	Bag, Carry, DCD-01, Single
600-1002	Wet Brush, Single
600-1003	Spray Bottle, DCD-01, Single
600-1004	Headband, Single
100-1002	Patient Guide, DCD-01, EN (Global English)
100-1005	Patient Guide, DCD-01, ES (Global Spanish)
100-1006	Patient Guide, DCD-01, DE (Global German)
100-1007	Patient Guide, DCD-01, IT (Global Italian)
100-1003	User Manual, Professional, DCD-01 (English)
100-1004	User Manual, Professional, DCD-01 (German)
100-1008	User Manual, Professional, DCD-01 (Italian)
700-1001	Assy, Hose, Therapy, DCD-01
700-1002	Assy, Hose, Prime, DCD-01
700-1003	Assy, Hose, Drain, DCD-01
700-1004	Power Cord, 15A/125V, C19, 3M, US
700-1005	Power Cord, 16A/ 250V, C19, 3M, EU
700-1006	Power Cord, 16A/ 250V, C19, 3M, UK
700-1007	Air Filter, Front, Airbox, DCD-01
700-1008	Air Filter, Side, Airbox, DCD-01
700-1009	Air Filter, Front, Battery-box, DCD-01
700-1010	Air Filter Kit, DCD-01 (includes all 4 Air Filters)

CK

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REVISION HISTORY

Version 01 Effective on 20-Oct-2022

Initial

Version 02 Effective on 04-Sep-2023

CR-2023-028 Clarification of CE revision

DOCUMENT ELECTRONIC SIGNATURES

DOCUMENT APPROVAL WORKFLOW

Author Approval

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I am the author of this document.

Signed 8:47:32 AM UTC 04-Sep-2023

Additional Steps Added

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I have reviewed and approve this document.

Signed 8:58:02 AM UTC 04-Sep-2023

Johan Johansson

VP of R&D & Operations

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I have reviewed and approve this document.

Signed 8:49:30 AM UTC 04-Sep-2023