

NCCD DECLARATION OF CONFORMITY

Contents

1. Manufacturer	1
2. Declaration of conformity	1
3. Object of the declaration	2
a) NCCD components:	2
b) Intended use.....	2
c) Unit information.....	3
4. Standards.....	3
5. Trade (Import/Export) compliance data	3
6. Product materials off-gassing.....	3
7. Documentation and internal references.....	4
8. Sign	4

1. Manufacturer

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2. Declaration of conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

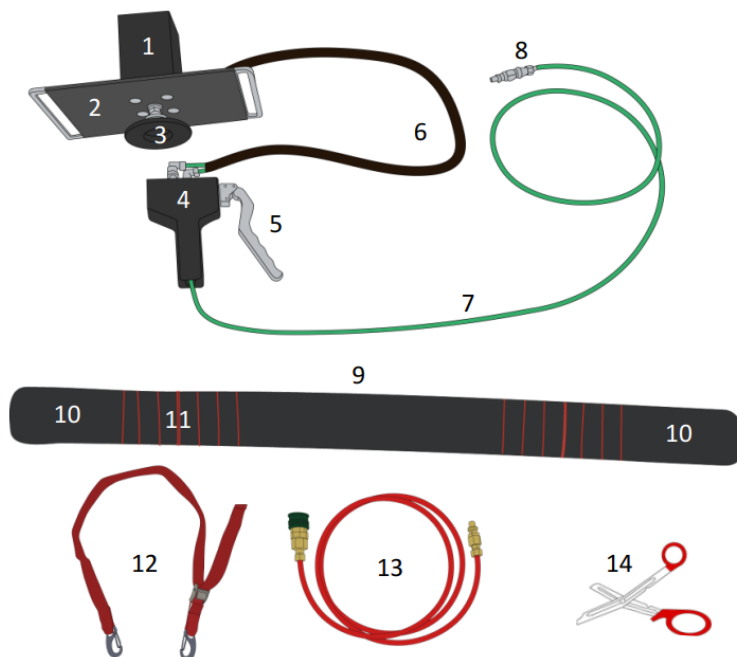
3. Object of the declaration

Product number: 902007-01

Object: Nui Compact Chest Compression Device (NCCD).

NCCD is a compact, lightweight external chest compression device. The NCCD is powered by compressed gas and designed for use in hyperbaric environments. NCCD will function while wet. The NCCD is gas driven and has no electrical parts.

a) NCCD components:



Parts:

- | | |
|-------------------------------|--|
| 1-3. Compression unit | 8. Hanson 600 series, 1/4" male coupling |
| 1. Piston house | 9. Chest belt |
| 2. Bottom plate | 10. Velcro |
| 3. Piston foot | 11. Red markings on chest belt |
| 4. Hand control unit | 12. Adjustable support strap |
| 5. Compression release handle | 13. Extension hose (150 cm) |
| 6. Pressure hoses (100 cm) | 14. Scissors for cutting fabric |
| 7. Pressure hose (200 cm) | |

b) Intended use

The NCCD is only to be used as a substitute to manual external chest compressions during cardiopulmonary resuscitation (CPR). The NCCD shall only be used when CPR is initiated on adult patients, and only by personnel that have sufficient CPR training.



c) Unit information

Specifications

Operating temperature: 5°C (41F) to 60°C (140F).

Noise level at operating distance: ≤80 dB.

Storage temperature: 5°C (41F) to 40°C (104F).

Maximum ambient pressure: 30 bar (435 psi/300 msw).

Requirements

Gas drive pressure: 10 bar (145 psi) over ambient.

Chest circumference: 90-130 cm (31-51 in).

Dimensions

(NCCD sealed unit and NCCD Training unit)

Case size (Peli1300): W270 x D246 x H174 mm

NCCD [1-9] weight: 1950 g

Complete set weight: 3480 g

Chest belt [9]: L150 cm, W11 cm

4. Standards

The NCCD is manufactured in conformance with the following standards:

ISO 9001:2015 Quality management systems

ISO 13485:2016 Medical devices - Quality management systems

ISO 14971:2019 Risk management to medical devices

ISO 12100:2010 Machine safety

NORSOK U-100 Manned underwater operations | Hyperbaric exposure limits

5. Trade (Import/Export) compliance data

Product: Nui Compact Chest Compression Device (NCCD).

Harmonized System (HS) Code: 90189080

Country of origin: Norway

6. Product materials off-gassing

The NCCD is off-gas tested in heliox 2% atmosphere at 10 bar atmospheric pressure.

The NCCD off-gassing is in compliance with NORSOK U-100 | Hyperbaric exposure limits.

7. Documentation and internal references

3663 NDDC Test protocol - Prototype final
3661 NUI rapport 2021-52 NCCD full kit off-gas testing
3664 NCCD Burst testing hoses and fittings
3665 NCCD Test protocol - Strekktest av slanger og fittings
3662 NUI Report NCCD Hygiene
3149 Procedure for production of NCCD
2952 Procedure for maintenance of NCCD
3035 NCCD User Manual

8. Sign



Rolf Røsland

CEO

NUI As