

Member State of OIML
United Kingdom of Great Britain
and Northern Ireland

OIML Certificate No
R76/2006-GB1-16.12

OIML CERTIFICATE OF CONFORMITY

Issuing authority: **NMO**
Person responsible: **Max Linnemann – Head of Certification Body**
Applicant:

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23542 Lübeck
Germany

Manufacturer: **The applicant**

Identification of the
certified pattern: **Babyleo TN500**

This certificate attests the conformity of the above-mentioned pattern (represented by the samples identified in the associated test report) with the requirements of the following Recommendation of the International Organisation of Legal Metrology (OIML):

OIML R 76 - Edition 2006(E) for accuracy class: [III]

This certificate relates only to the metrological and technical characteristics of the pattern of the instrument concerned, as covered by the relevant OIML International Recommendation.

This certificate does not bestow any form of legal international approval.

Important note: Apart from the mention of the certificates reference number and the name of the OIML Member State in which the certificate was issued, partial quotation of the certificate or of the associated test report is not permitted, though they may be reproduced in full.

Issue Date: 25 November 2016



Marek Bokota
Technical Manager
For and on behalf of the Head of Certification Body

NMO | Stanton Avenue | Teddington | TW11 0JZ | United Kingdom
Tel +44 (0) 20 8943 7272 | Fax +44 (0) 20 8943 7270 | Web www.gov.uk/government/organisations/regulatory-delivery
NMO is part of the Regulatory Delivery directorate within the Department for Business, Innovation & Skills



0135

The conformity was established by testing and examinations described in the associated Evaluation Report P01847 which includes 15 pages.

Characteristics of the instrument:

The Drägerwerk Babyleo TN500 is a Class III, mains operated, self-indicating, non-automatic weighing instrument designed for medical use as a baby weigher and incubator / warming bed.

The instrument shall not be used for direct sales to the public.

Main features:

- Galvanised steel supporting frame on wheels, with height adjustable support structure
- Plastic bassinet frame with canopy, mounted on the support structure
- Radiating heat lamp fixed above the canopy
- Plastic weighing platform comprising four load cells, analogue to digital converter, and microcontroller to process the digital weight signal (scaling).
- User interface comprising a touch-screen display and push/rotate knob
- Plastic mattress tray on the weighing platform
- Softbed mattress or heated mattress on the mattress tray
- Ventilation fan below the weighing platform
- Pedals to adjust the height of the bassinet
- Keys on bassinet frame to adjust the longitudinal tilt and adjust the height of the weighing platform.

Devices:

- Tare balancing
- "Weigh", "Re Weigh" and "Adjust" functions
- Gravity compensation
- Data storage

Load cell:

The instrument is fitted with four load cell type Planar Beam, $E_{max} = 7.5$ kg manufactured by Flintec.

Metrological characteristics:

Max	10 kg
Min	200 g
e =	5 g
T ≤	- 3 kg

The temperature range for the instruments is +15 °C / +45 °C.

Software:

All legally relevant functions are contained within the In-Bed Weighing Platform. The In-Bed Weighing Platform consists of the scale application and the boot loader. The boot loader is executed at power on, calculates the checksum of the scale application and starts execution if the checksum is okay.

The scale application firmware is designated 3.22.

Any change to calibration data or firmware version will increment the non-resettable adjustment counter.

The location of the instrument is input at installation to allow gravity compensation; any change to the geographical position information will increment the non-resettable geographical position counter. The geographical position information is held on the incubator device.

The scale application version number, adjustment, and geographical position counters are displayed by navigating to 'System setup > System > Service (requires password) > Service menu > Operating Data > Scale.

Interfaces:

- RJ45
- USB
- Serial Port
- Temperature sensors
- Nurse call
- Audio input
- Scale input

Sealing measures:

All legally relevant parameters are stored/provided by the weighing platform. Access to the electronics, load cell and ADC is prevented by sealing labels covering the 6 screws that seal the weighing platform.

The value of the adjustment counter described under Software must be written on a tamper-evident label on the side of the weighing platform.

The value of the geographical position counter described under Software must be written on a tamper-evident label on the back of the display.

All weighing platforms are calibrated identically and geographical position is held on the incubator.

CERTIFICATE HISTORY

ISSUE NO.	DATE	DESCRIPTION
R76/2006-GB1-16.12	25 November 2016	Certificate first issued.
-	-	No revisions have been issued.