

Issued by NMI Certin B.V.,  
designated and notified by the Netherlands to perform tasks with respect to conformity modules mentioned in Article 13 of Directive 2014/31/EU, after having established that the measuring instrument meets the applicable requirements of Directive 2014/31/EU, to:

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

Measuring instrument **A Non-automatic weighing instrument**  
Type : Babyleo TN500

Further properties are described in the annexes:  
– Description T11461 revision 2;  
– Documentation folder T11461-1.

Valid until 7 February 2029

Remark This revision replaces the earlier version, except for its documentation folder.

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#### Certification Board

**NMI Certin B.V.**  
Thijssseweg 11  
2629 JA Delft  
The Netherlands  
T +31 88 6362332  
certin@nmi.nl  
www.nmi.nl

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## 1 General information about the non-automatic weighing instrument

All properties of the non-automatic weighing instrument, whether mentioned or not, shall not be in conflict with the legislation.

### 1.1 Essential parts

The electronics;  
 The mechanical assembly with load cell.

See block diagram;

Number	Pages	Description	Remarks
11461/0-01	1	Block diagram	-

EMI protection measures:

- Ferrite on cable between scale PCB and load cells;
- Ferrite on cable between PI-board and Mattress scale board;
- Ferrite on external scale cable;
- T500 AC board Mains filter (discrete).

### 1.2 Essential characteristics

Accuracy class		III		
Application		Designed for medical use as a baby weigher and incubator/warming bed		
Software identification	Product software	1.01 and 1.02	1.04	1.05 or 1.xx.xx (xx=00...99)
	Scale application software	3.22		4.02
Maximum capacity		Max ≤ 10 kg		
Verification scale interval		e ≥ 5 g	e ≥ 10 g	
Weighing range		Single interval		
Maximum number of scale intervals		n ≤ 2000	n ≤ 1000	
Tare		T ≤ -3 kg	T ≤ -5 kg	T ≤ -10 kg
Temperature range		+ 15 °C / + 45 °C		
Power supply voltage		100 – 240 V AC 50/60 Hz		

The product software version is displayed by navigating to System setup > System > Service.



The Scale application software version is displayed by navigating to System setup > System > Service > Service menu > Operating Data > Scale.

The embedded software device and Scale application software is tamper proof by the CRC checksum.

The installed product and scale application software are labelled outside on the device, or can be verified on the designated operation menu (password protected).

The password of the operation menu in normal operation mode is "0000". This password can be changed by the user.

The non-automatic weighing instrument has embedded software.

### 1.3 Essential shapes

Number	Pages	Description	Remarks
11461/0-02	2	Outlines	-

The data plate is secured against removal by sealing or will be destroyed when removed.

Inside the cabinet is an adjustment lock, located on the main board.

### 1.4 Conditional parts

The non-automatic weighing instrument may be equipped with peripheral equipment which is used for the applications listed in Article 1(2), (a) to (f) of Directive 2014/31/EU, provided that the peripheral equipment is certified to be connected to a non-automatic weighing instrument by a Notified Body responsible for type examination under Directive 2014/31/EU, or, that the equipment and the use of the equipment complies with the requirements of WELMEC 2.5 Issue 2 clause 2.2.

The non-automatic weighing instrument is fitted with a levelling device and a level indicator, unless the instrument is installed in a fixed position. A ring on the level indicator indicates when the maximum tilt is exceeded.

The non-automatic weighing instrument may be equipped with one or more of the following protective interfaces that have not to be secured:

- RJ45;
- USB;
- Serial port;
- Temperature sensors;
- Nurse call;
- Audio input;
- Scale input.

## 1.5 Non-essential parts

The non-automatic weighing instrument may be connected to non-essential devices provided that:

- They do not present primary data used for purposes mentioned in Article 1(2), (a) to (f) of Directive 2014/31/EU unless the "Preliminary observation" in Annex I of the Directive is satisfied;
- They do not lead to an instrument having other essential characteristics than those fixed by this certificate.

## 2 Information about the main constituent parts of the non-automatic weighing instrument

### 2.1 The electronics

#### 2.1.1 Essential parts

Number	Pages	Description	Remarks
11461/0-03	3	A/D board	Including parts list

#### 2.1.2 Essential characteristics

List of legally relevant functions:

- Gravity compensation;
- Semi-automatic combined zero-setting and tare balancing device;
- Subtractive tare;
- Preset tare-device (weight values can be manually adjusted, and shall be clearly labelled as adjusted weight);
- Device for weighing unstable samples;
- Data storage;
- Acting upon significant faults;
- Checking the display;
- Check weighing;
- Weigh function (activates the weighing process, taring is performed before weighing);
- Reweigh function (restarts the weighing process, taring step is omitted when pressed).

When the instrument is used for weighing patients the following legally relevant function may be present:

- Offset compensation (an alternative for initial zero setting in the range of  $\pm 1000$  g which can be accessed in the internal service menu. The use of this function will not increase the value of the event counter).

#### 2.1.3 Non-essential parts

Guided User Interface (GUI).

## 2.2 The mechanical assembly with load cell

### 2.2.1 Essential parts

Number	Pages	Description	Remarks
11461/0-04	1	Load cell assembly	-
11461/0-05	1	Load cell specification sheet	-

### 2.2.2 Essential characteristics

$e \geq E_{\max} / 1500$ ;  
 Excitation voltage 5 V DC.

### 2.2.3 Essential shapes

See 2.2.1.

## 3 Seals

To secure components that may not be dismantled or adjusted by the user, the non-automatic weighing instrument has to be secured in a suitable manner on the locations indicated in the drawing:

Number	Pages	Description	Remarks
11461/0-06	1	Sealing	-

## 4 Conditions for conformity assessment

The marks, facilities for the marks and the inscriptions on the non-automatic weighing instrument fulfil the requirements of point 1 of Annex III of Directive 2014/31/EU.

Conformity assessment needs to be performed without baby mattress or support walls, and only with the plastic mattress tray. For software versions 1.01, 1.02 or 1.04 to compensate for the absence of the zero function, a load has to be applied manually for the case of a negative offset. For software version 1.05 or higher, the integrated semi-automatic combined zero-setting and tare balance device shall be used to zero the scale (System setup > System > Service > Service menu > Operating Data > Scale).

The inscriptions contain the value of the event counter.