

	
<b>OIML Member State</b> United Kingdom of Great Britain and Northern Ireland	<b>OIML Certificate No.</b> <b>R76/2006-A-GB1-20.05</b> <b>Revision 1</b>
<b>OIML CERTIFICATE ISSUED UNDER SCHEME A</b>	
OIML Issuing Authority <b>NMO</b> <b>Stanton Avenue</b> <b>Teddington</b> <b>TW11 0JZ</b> <b>United Kingdom</b>  Person responsible: <b>Mannie Panesar – Head of Technical Services</b>	
Applicant <b>Stryker Medical</b> <b>3800 E Centre Avenue</b> <b>Portage, MI 49048</b> <b>USA</b>	
Manufacturer <b>The applicant</b>	
Identification of the certified type <b>MV3™ Bariatric hospital beds 5900 series</b> <i>(the detailed characteristics are defined in the Descriptive Annex)</i>	
<p>This OIML Certificate attests the conformity of the above identified type (represented by the sample(s) identified in the OIML type evaluation report) with the requirements of the following Recommendation of the International Organization of Legal Metrology (OIML):</p> <p><b>OIML R 76-1, Edition: 2006</b></p> <p>For accuracy class: IIII</p>	
Issue date: 14 September 2020  <b>The OIML Issuing Authority</b>    <b>Grégory Glas</b> <b>Lead Technical Manager</b> <i>For and on behalf of the Head of Technical Services</i>	

This OIML Certificate relates only to metrological and technical characteristics of the type of measuring instrument covered by the relevant OIML Recommendation identified above.

This OIML Certificate does not bestow any form of legal international approval.

The conformity was established by the results of tests and examinations provided in the associated OIML type evaluation report:

No. P02722 dated 29 May 2020 that includes 16 pages

The technical documentation relating to the identified type is contained in documentation file:

No. P02722-D dated 29 May 2020

#### **OIML Certificate History**

<b>Revision No.</b>	<b>Date</b>	<b>Description of the modification</b>
Revision 0	29 May 2020	Certificate first issued.
Revision 1	14 September 2020	Section Software: addition of gravity zone setting. Section Sealing: addition of gravity zone of operation.

This revision replaces previous versions of the certificate.

*Important note:*

*Apart from the mention of the Certificate's reference number and the name of the OIML Member State in which the Certificate is issued, partial quotation of the Certificate and of the associated OIML type evaluation report(s) is not permitted, although either may be reproduced in full.*

## DESCRIPTIVE ANNEX

### Characteristics of the instrument:

The Stryker MV3™ Bariatric hospital bed 5900 series are hospital beds incorporating a Class III, mains and / or battery operated, self-indicating, non-automatic weighing instrument. The height and surface contours of the bed are adjustable. The bed includes movable and latchable siderails, adjustable litter deck width, and control boards.

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

### Main features:

- Hospital bed, with weighing control and display functions on the footboard.
- Control panel and display.
- Four load cells installed at the four corner positions of the bed base.
- Siderails incorporating attendant clinician and patient controls for height control and surface contours control buttons.
- Adjustable litter deck width (91.44cm, 106.68cm and 121.92cm, corresponding to 36", 42" and 48")

### Devices:

- Combined semi-automatic zero setting device and semi-automatic tare balancing device.
- Zero enunciator.
- "Weight history" function.
- "Change equipment" function.
- Gravity compensation is set by selecting the appropriate region of operation in the maintenance menu.

### Load cell:

The four load cells are each a HBM shear beam load cell, model K-SBS, Emax = 453.592 kg. The load cells are connected to two scale board PCBAs and those PCBAs are coupled via a communication harness.

### Operation

#### • **Switch-on**

At switch-on, the display screen shows the status of the bed to ensure that the bed has no defect. Any error code would trigger a "Error Code XX.XX" warning and associated features would be disabled.

#### • **Weigh function**

The Weigh function is used to operate to display and log the patient weight. The current weight is displayed for 10 seconds before being shown in the "Last weight" reading section. After 5 minutes without interaction or critical error the display goes to sleeping mode.

Unstable / real time weight readings are not shown while stable weights are displayed in the line of Last weight. After the next weigh operation, the previous weight is displayed in the Weight

history.

- **Combined semi-automatic zero and tare setting function**

The bed can be zeroed via Zero/Tare function, provided that it is within +4% of the maximum capacity around the calibrated zero.

When the weight is over 4% of the maximum capacity, the tare setting device operates via the same Zero/Tare scale function and "NET" is displayed below the weight indication.

The Zero/Tare function displays the date and time of the most recent zero/tare operation.

- **Under weight and over weight**

">max" is displayed instead of the weight indication if the weight is more than 518 kg.

"->0<-" is displayed instead of the weight indication if the weight is within 0.25e of Gross zero.

Negative weights less than -0.25e result an error message of "<min" and the weighing function is prohibited.

"<min" is displayed instead of the weight indication if the weight is below Minimum capacity.

- **"Weight history" function**

This function displays the previous 10 weighing values for information only.

- **"Change equipment" function**

As it may be necessary to add or remove medical equipment to or from the weighing part of the bed, this function allows additional tare values to be weighed without affecting the net weight displayed.

- **Scale system errors**

If an error is detected the text "Scale Uncalibrated" or "Error Code XX.XX" is displayed instead of weight (defective sensor, etc). In the case of unstable weights, the error message "Scale unstable" is displayed.

The load cells are mounted on the frame via swing link with bushings and self-centred by gravity. The weighing platform may be tilted at a maximum 2.86 degrees.

Each error is logged and available for review in the maintenance menu. The maintenance menu is password protected.

Technical data:

The instrument operates on a 230 VAC 50 Hz main supply. The instrument can also operate on two 12V batteries, which are rechargeable during the operation.

The operating temperature range for the instruments is +5 °C / +35 °C.

	MV3 5900
Accuracy class	III
Maximum capacity, Max	500 kg
Minimum capacity, Min	102 kg

Verification scale interval, e =	2 kg
Number of intervals n	250
Maximum tare, T	- 80 kg

Software:

The MV3 Scale software (SMB) software is installed as compiled code, as an executable file, and as such cannot be modified using common software tools. Access to the legally relevant parameters and download of the software is protected by two-step passwords; a non-editable log (incrementing “calibration counter”) provides evidence of intervention. Download of software is prevented by the hardware sealing method described below.

The calibration counter is displayed next to the “Calibrate scale” menu item and can be accessed via:

Settings → Maintenance → (Input 1<sup>st</sup> pass code “246” via arrow button) → Scale maint → (Input valid 2<sup>nd</sup> pass code via arrow button) → Calibrate scale yy (where yy is the current value of the calibration counter).

The gravity zone setting can be accessed via:

Settings → Maintenance → (Input pass code “246” via arrow button) → Zone of Operation Zone z (where z is the current value of the gravity zone). Note that gravity zones are defined in the MV3 maintenance manual.

The software identification can be displayed by selecting Settings → About.

The legally relevant part of the software shall be as follows:

Scale Board	Head	Foot
Part Number	590048005401	590048005402
Software Version	1.20.01.01	1.20.01.01

Interfaces:

There is currently no authorised interface.

Approval Conditions:

The instrument shall not be used on unlevel flooring exceeding a 2.86 degrees tilt angle.

Sealing:

Access to the Load cell cable and analogue to digital converting PCB are sealed by tamper evident labels.

The values of the calibration counter and gravity zone of operation specified in the Software Section shall be written on the rating plate. In the event of removal or load cell disconnection, software will force a recalibration of the system.

Alternatives:

There are currently no authorised alternatives