

Declaration of Conformity

Directive 93/42/EEC, medical equipment and automatic weighing instruments Directive 90/384/EEC

MENSOR

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I conclude that medical scales of our production, the following below mentioned types meet European standards in the ISO / IEC 45501, and Council of Europe: 93/42/EEC for the first class of medical devices with measuring function and Directive 90/384/EEC for automatic weighing instruments.

Type of scale:

<i>description</i>	<i>designation PL</i>	<i>designation DE</i>	<i>serial number</i>	<i>amount</i>
scales for baby weighing	WE15P2	PCE-PS-15 MBS		
scales for baby weighing	WE20P2	PCE-PS-20 MBS		
personal medical scale for man	WE150P1	PCE-PS-150 MPC		
personal medical scale for man	WE200P1	PCE-PS-200 MPC		
medical chair scale	WE150P3 K	PCE-PS-150 MCS		
personal scale with mechanical measuring syst.	WE150P3 M	PCE-PS-150 MM		
personal scale with mechanical measuring syst	WE200P3 M	PCE-PS-200 MM		
personal scale with electronic measuring system	WE150P3 W	PCE-PS-150 MA		
personal scale with electronic measuring system	WE200P3 W	PCE-PS-200 MA		
personal scale with the display on the pipe arm	WE150P3	PCE-PS-150 MPS		
personal scale with the display on the pipe arm	WE200P3	PCE-PS-200 MPS		
medical bad scale	WE300P1 L	PCE-PS-300MBW		
bariatric scale	WE200P4	PCE-PS-200 MSH		
special scale for weighing patients in wheelchair	WM150P1 50x90Z	PCE-PS-150 MXL		

We hereby declare that the above medical scales meet the requirements of Annex V and Annex I of Council of the European Economic Community No. 93/42/EEC of 24 June 1993, implemented into Polish law of Medical Devices Act of 20 April 2004 and the Decree of the Minister of Health of 3 November 2004 on the basic requirements for medical devices for various purposes and the following harmonized standards: PN EN 45501, EN 61010-1, European Council Directive 73/23/EEC (Low Voltage Directive), PN 1041-2009, PN EN ISO 14971 - 2009, ISO 13485, BS 60950-2000, PN EN 60065:2001, EN 55022:2000, PN EN 55013 + A: 1997

Conformity assessment according to Annex V of Directive 93/42/EEC was performed with the involvement of a Notified Body No. 1434, and in / g directive 90/384/EEC Notified Body No. 1440th

Obtained Certificate of EC Type Approval No. PL 06 003 dated 21-04-2006 the Central Office of Measures.
Obtained Certificate of Conformity No. MD - 220/1/2009 date of application of the CE mark – 2009.

Warsaw 2009

A stylized handwritten signature in black ink, appearing to be 'J. Lewandowski', written over the word 'Manager'.

dr inż. Janusz Lewandowski