AMIDENT
Jacek Kałużny
ul. Dzielna 5/1a
00-162 Warszawa

Warsaw 16.04.2014 r.

Declaration of conformity / statement regarding the medical device.

The declaration was made on the basis of the Act of 20.04.2004 (Journal of Laws of 2004 No. 93 item 896 of 2005 No. 64 item 565) and the Regulation of the Minister of Health of November 3, 2004 on essential requirements for medical devices for various purposes.

Please be advised that the prophylactic sand Monoflow registered in the Department of Information on Medical Devices UR.DIM.IMZ.410.00270.2014.PM1.3 as a medical device Monoflow, meets the requirements of the Act on Medical Devices of 20.04.2004.

The provisions of the Act implement the provisions of the directives:

90/385 / EEC of 20 June 1990 relating to active implantable medical devices.

93/42 / EEC of 14 June 1993 concerning medical devices.

I hereby declare that the medical device Monoflow mentioned above is a medical device of the first class, the first rule and corresponds to the essential requirements.

The entity responsible for drawing up the declaration of conformity:

Manufacturer of Monoflow - Amident, Jacek Kałużny
ul. Dzielna 5 / 1a, 00-162 Warszawa NIP 563-166-98-09 Regon 012685313
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