Aflofarm Farmacja Polska Sp. z o.o.
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DECLARATION OF CONFORMITY NO.1/2019

I, the undersigned:

Hanna Wahl – Member of the Management Board

Company name: Aflofarm Farmacja Polska Sp.z o.o.

ul.Partyzancka 133/151

95-200 Pabianice

As the owner of the medical devices listed below, hereby declare that it pursuant to Rule no.5 of the Regulation of the Minister of Health of 5 November 2010 on Qualification of Medical Devices.

The device meets the essential requirement of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as amended by Directive 2007/47/EC, the Act of 20 May 2010 on medical devices (Journal of Laws 2010 No.107, item.679) and Annex I of the Regulation of the minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures for medical devices (Journal of Laws 2011 No.16, item 74). The device is safe for the patient and does not pose a risk to the user and third parties when used as intended.

Particulars of Medical Device:

Name of Device	Kit for nose and sinus rinse
Model	- Irigasin Set (Kit for nose and sinus rinse, 12 sachets and irrigator 240ml) - Irigasin Sachets (Complememtary kit for nose and sinus rinse, 30 sachets)
Manufacturer	Aflofarm Farmacja Polska Sp.z o.o.
Country of Origin	Poland
Classification	Class I
Applied Standard	EN ISO 13485:2012+AC:2012

Pabianice, 10.06.2019

CZŁONEK ZARZĄDU
Hanna Wahl