

date: 20.12.2020

rev.: 1



CE DECLARATION OF CONFORMITY FOR PSS LIANA

ASP Polska Sp. z o.o.
ul. Wierzbowa 21
67-200 Głogów

Herewith ASP Poland declares that the medical device product "PSS LIANA" range described below, conforms with essential requirements and provisions of MDR 2017/745 Concerning Medical Devices.

This CE declaration is issued only under the responsibility of the manufacturer, which is ASP Polska.

The Basic UDI-DI as referred to in Part C of Annex VI will be assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability.

The device is categorized as risk class 1 as per Annex VIII, rule 12.

The device is not sterile, does not have a measuring function and is not invasive.

The declaration was issued on the basis of the following harmonized standards: PN-EN 12182; PN-EN 60601.

The declaration was issued on 20.12.2020 in Głogów at the seat of the ASP Poland.

Signature:

A handwritten signature in blue ink, appearing to read 'Stefan Löcker', written over a horizontal line.

Managing Director Stefan Löcker