

DECLARATION OF CONFORMITY EU

According to the Annex IX of the directive 93/42/EEC

We,

BOW MÉDICAL

43 Avenue d'Italie
80000 Amiens - France
SRN: FR-MF-000011517

guarantee and declare under our sole responsibility that the medical device:

Prescription tool DIANE

Class I according to the Annex IX of the directive 93/42/EEC

Complies with rule 12 of Annex IX of the directive 93/42/EEC, the standard IEC 62304 « Medical device software - *Software life cycle processes* » and meets the requirements of the article 120 « transitional provisions » of the Medical Device Regulation 2017/745

This declaration of conformity is issued under the sole responsibility of the manufacturer.

DIANE version: 4.12

DIANE Medical Device version: 3.38

UDI-DI : (01)3760404900005(10)0338

Place and date: At Amiens, France, on **19/02/2024**

President: Pierre TOUTON

