

BM-QUA-EN-040 Version 02 MAJ 10/11/2022 Diffusion : B- Client

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 directive93/42/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 responsability of the manufacturer.

DIANE version: 4.11

DIANE Medical Device version: 3.28

Place and date: At Amiens, France, on 17/03/2023

President: Pierre TOUTON

43 avenue d'Italie - 80090 AMIENS 0891 700 300 (0,25 cts/min) +33 (0)3 60 03 24 68 Fax : +33 (0) 9 72 29 34 87 Mail : contact@bowmedical.com SAS au capital de 101 108€ SIRET : 424 281 392 00045 - APE 6201Z Code TVA FR03424281392 RCS AMIENS B 424 281 392 N° Compte : 30003 00070 0020636548 87 BIC : SOGEFRPP IBAN FR76 3000 3000 7000 0206 3654 887