PRINCE MEDICAL
ZAC De la Sente du Moulin 60530 Ercuis
FRANCE

EC DECLARATION OF CONFORMITY

According to the European Directive 93/42/EEC, PRINCE MEDICAL guarantees and declares under its own responsibility as manufacturer that the medical devices described below, are compliant with the requirements applicable to European Directive 93/42/EEC amended by Directive 2007/47/EC as class **[Is]** medical devices as defined by rule **[5]** of Annex IX and CE marked in accordance with:

☐Annex II (excluding point 4 amended by Directive 2007/47/EC) and V point 3 and 4 of European Directive 93/42/EEC

☒Annex VII and V point 3 and 4 of European Directive 93/42/EEC amended by Directive 2007/47/EC

Medical Device file No. :	**DT016 – HYSTEROMETRE**
EMDN Code :	**U089003 : HYSTEROMETERS**
BASIC UDI-DI :	**3665039HYST**
Manufacturer:	**PRINCE MEDICAL - *ZAC de la Sente du Moulin - 60530 Ercuis - FRANCE***

Trade name	Reference	Designation	Class and rule	UDI
PM-CARE®HYSTEROMETRE	PS1251000	Hystéromètre CH10 *Hysterometer CH10*	Is (Rule 5)	3665039003254
PM-CARE®HYSTEROMETRE	PS1251200	Hystéromètre CH12 *Hysterometer CH12*	Is (Rule 5)	3665039003261
PM-CARE®HYSTEROMETRE	PS1251400	Hystéromètre CH14 *Hysterometer CH14*	Is (Rule 5)	665039003278

Notified body: GMED - CE 0459

Devices covered by CE Certification:

☐ 9161 rev.16 and its supplement No. 37803 rev.1 extending the validity of the certificate to 2028 or until the certificate is obtained under MDR 2017/745 amended by Regulation (EU) 2023/607 of March 15th, 2023 in accordance to the manufacturer's Declaration in relation to regulation (EU) 2023/607 and (EU) 2017/745.

☒26672 rev. 13 and its supplement No. 37804 rev.1 extending the validity of the certificate to 2028 or until the certificate is obtained under MDR 2017/745 amended by Regulation (EU) 2023/607 of March 15th, 2023

Done at Ercuis on: May 23th, 2024

HERBERT Kim
Quality, Regulatory Affairs and Site Director