COXO®
Professional Dental Manufacturer
SINCE 2003

Foshan COXO Medical Instrument CO., LTD.
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Statement Letter

We Foshan COXO Medical Instrument Co., Ltd as the manufacturer of devices listed on the CE certificate (Certificate No.: DD 60151346 0001), hereby declare the following:
(a) those devices continue to comply with Directive 93/42/EEC;
(b) there are no significant changes in the design and intended purpose;
(e) the device s do not presentan unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) no later than 26 May 2024, we has put in place a quality management system in accordance with Article 10(9} of MOR;
{e) no later than 26 May 2024,we has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.
" In accordance with Regulation (EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU} 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, the above-mentioned CE certificate shall remain valid after the end of the period indicated on the certificates until December 31,2028.

SIGNATURE AND STAMP