Declaration of Conformity

For the following products:

Dental Unit
(Product Name)

S90, S60, S30, U100, U200, U500(FAGI), V1000(VEGA), V2000, V5000, V6000
(Model designation)

is hereinafter confirmed to comply with the requirement set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive(93/42/EEC As amended by 2007/47/EC)
EN ISO 13485:2012; EN ISO 14971: 2012; EN980:2008; EN 1041:2008+A1: 2013; EN ISO 15223-1:2012; EN 60601-1-2:2015; EN 60601-1:2006+A1:2013; EN 62304:2006+A1:2015; EN1640:2009; EN ISO 9680:2014; EN ISO 7494-1:2011; EN ISO 7494-2:2015; EN ISO 6875:2011; EN 60601-1-6:2010+A1:2015; EN 62366:2008+ A1:2015;EN 80601-2-60:2015; EN ISO 10993-1:2009/AC: 2010;EN ISO 10993-5:2009; EN ISO 10993-10:2010

Conformity Assessment Route:
Annex II excluding section 4 of Medical Device Directive

Notified Body:
DNV GL Nemko Presafe AS(NB No.2460)
Veritasveien 3, N-1363 Høvik Postbox 116, N-1300 Sandvika

The following representative in Europe is responsible for making this declaration:

Company Name: CGI Business Trading and Consulting e.K

Company Address: Hans-Bethe-Str.1, 60438 Frankfurt am Main, Germany

The following manufacturer is responsible for making this declaration:

Company Name: Zhuhai Siger Medical Equipment Co., Ltd.

Company Address: Building 2, No.1 Chuangxin Yi Road, Tangjiawan Town , Zhuhai City Guangdong Procince, P.R. China

总经理请签名	General Manager	日期
		2017-6-28
(Legal Signature)	(Position/title)	(Date)

Digitally signed by Priscu Victor
Date: 2019.10.25 16:13:58 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA S.R.L. "VIVIMED PLUS" IDNO 1011600009486 SOCIETATEA CU RASPUNDERE LIMITATA