SCHILLER
The Art of Diagnostics

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Regulatory compliance statement acc. EU 2017/745

To whom it may concern,

We, SCHILLER AG, confirm the compliance of the following activities according to the Medical Device Regulation (EU) 2017/745 (MDR):

- Post marketing surveillance (Article 83 to 86, Article 92 and Annex III)
- Vigilance (Article 87 to 92)
- Registration of economic operators (Article 31)

In accordance with Article 120 regarding transitional provisions of Regulation (EU) 2017/745 (MDR) the following devices are in conformity with the Directive 93/42/EEC (MDD) and remain valid until the end of the period indicated on the EC-certificate. The EC-certificate of the following devices remains valid until 2024-04-16.

CARDIOVIT CS-104
CARDIOVIT CS-200 Excellence
CARDIOVIT CS-200 Office
CARDIOVIT AT-180
CARDIOVIT AT-102 G2
CARDIOVIT AT-1 G2
CARDIOVIT MS-2010/2015
medilogAR
medilog DARWIN2
MS-12 blue
DIAGNOSTIC STATION DS20
SPIROVIT SP-1 G2
Tempus LS
ARGUS PRO LifeCare 2
ARGUS LifePoint
ARGUS LifePoint 2
ARGUS PB-1000
FRED easyport
FRED easyport plus
CARDIOVIT FT-1
CARDIOVIT AT-1 G2
SEMA
EASY PULSE
BR-102 plus
BR-102 plus PWA
BP-200 plus

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