EC Certificate Full Quality Assurance System: Certificate BG19/871871

The management system of

VISARIS doo

Batajnički drum 10. deo 1b, 11080 Belgrade, Serbia

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Visaris Avanse family of digital x-ray diagnostic imaging systems
Visaris PACS (Picture Archiving and Communication system)
Diagon (Medical imaging diagnostic workstation)
Vision family of X-ray systems (ddRAura Series, ProXima Series)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 27 October 2020 until 17 August 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 17 August 2006
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered BG/SOF 213593

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Digitally signed by Matei Vasile
Date: 2022.04.08 09:28:26 EEST
Reason: Validation Signature
Location: Moldova