



bqs.
The Trust. We Make.



Notified body 2854 | SKTC-180

bqs, s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

Certificate MDD 21 038 0100

Full Quality Assurance System Certificate

Directive 93/42/EEC on Medical Devices Annex II excluding section 4

Certificate holder: **PROMOVET s.a.r.l**

1 ZAC route de Beauraing, 08600 Givet,
France

Related audit report: AMDD 2021NB038 I01

Other Facility(ies): -



The certificate was issued with respect to the following scope:

Droper Field 1000

Droper Field 500

This certificate is effective from 25th May 2021 until 26th May 2024 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 25th May 2021.

Certification has been authorized by

Digitally
signed by
Radovan Máčaj

Radovan Macaj
Head of Notified body

bqs.
Certified Medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 93/42/EEC, Slovak government decree No. 582/2008 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex II excluding section 4 of the directive and found that the quality assurance system meets the requirements laid down by Annex II. For the placing on the market of Class III devices an EC design-examination certificate according to Annex II section 4 is required, Please see also notes overleaf if any.



bqs.
The Trust. We Make.



Notified body 2854 | SKTC-180

bqs, s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

Additional information on certification

Related to certificate number:

MDD 21 038 0100



Description of product(s) within the certification scope:

Mechanical pressuriser of flexible fluid bags intended for peripheral intravenous infusion/transfusion.

Types/Categories/Models: DROP1000ER01, DROP500ER01

Classification: **Class IIa**
(in accordance with the Medical Devices Directive Annex IX Rule 11)

This certificate is effective from 25th May 2021 until 26th May 2024 and remains valid subject to execution of regular examinations and continuous compliance.

Initial version of the certificate was effective from 25th May 2021.

bqs.
Certified Medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 93/42/EEC, Slovak government decree No. 582/2008 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed examination of quality assurance system in accordance with Annex II excluding section 4 of the directive and found that the quality assurance system meets the requirements laid down by Annex II. For the placing on the market of Class III devices an EC design-examination certificate according to Annex II section 4 is required. Please see also notes overleaf if any.