Quirem Medical B.V. - A Terumo Company

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www.terumo-europe.com

March, 2023

Dear Customer,

With this letter, Quirem Medical B.V. – a Terumo company – would like to inform you that below mentioned Quirem Medical BV products and certificates, meet the requirements as stipulated in Regulation (EU) 2023/607, Article 1(1) 3c - amending MDR 2017/745, Article 120 - points (a) to (e).
As such, the certificates mentioned below, are extended, accordingly.

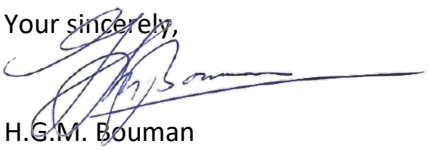
Product Group	**Classification (MDR)**	**(AI)MDD certificate number**	**Issue date (initial)**	**Original validity date**	**Extended validity date**
Q-Suite™ 2.x	Class IIb	2172702CE02	1 April 2015	1 April 2023	31 December 2028
QuiremScout™	Class III	2172702CE03 2172702DE02	1 April 2015	1 April 2023	31 December 2027
QuiremSpheres™	Class III	2172702CE01 2172702DE01	1 April 2015	1 April 2023	31 December 2027

Requirements met, as stipulated in (EU) 2023/607, Article 1(1) 3c points (a) to (e), are explained below:

(a) Above devices continue to comply with Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD), as applicable;
(b) There are no significant changes in the design and intended purpose of these devices;
(c) The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) Quirem Medical B.V. has put in place a quality management system in accordance with MDR Article 10(9);
(e) Quirem Medical B.V. has lodged a formal application with notified body DEKRA Certification B.V. (ID no 0344) for all above-mentioned devices and has signed a written agreement with this notified body.

Please be informed, re-certification under MDR is anticipated for on short notice. You will be informed, accordingly.

Your sincerely,



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