CERTIFICATE

EU Quality Management System Certificate – Annex IX

Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation
Regulation 2017/745 on MEDICAL DEVICES

The certificate:	**21M00096CRT01**
issued by:	**Kiwa Dare B.V.** **Vijzelmolenlaan 7** **3447 GX Woerden** **The Netherlands**
to:	
Manufacturer	**FastFocus B.V.**
Address	**Gerverscop 9** **3481 LT Harmelen** **The Netherlands**
SRN:	**NL-MF-000002981**

The scope of certificate comprises an EU quality management system regarding the following devices or groups of devices: Active non-implantable devices for monitoring of vital physiological parameters

This certificate is based on the following documents:
Audit report: 21M00096PRP02
TD report: 22M00033RPT01

Kiwa Dare B.V. hereby declares that it has audited the quality assurance system in accordance with MDR Annex IX, chapter I and III and that the relevant provisions of the Regulation 2017/745 dated May 5, 2017 concerning Medical Devices are fulfilled. The validity of this certificate is five years and includes the surveillance obligations of Annex IX, section 3. The products shown in the scope of certification are covered by this certificate and may bear the CE marking using the Notified Body number “1912”.

Issued for the first time:	**29-06-2023**	**Preceding certificates:**	**NA**
Reissued:	**NA**		
Valid to:	**29-06-2028**	**Date of identification of changes:**	**NA**

Kiwa Dare B.V.

DocuSigned by:
Nadia Vazirpanah
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Dr. N. Vazirpanah
Certification decision maker

Ing. D. Van der Vlugt
Director

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Appendix of EU Quality Management System Certificate – Annex IX

Devices/groups of devices	Risk classification	Intended purpose (only IIb and III)
Vital Signs Monitoring System 871932658731200V9 MDA0203	Devices in Class IIa	NA

The certificate: **21M00096CRT01**

The facilities covered by this certificate are:
FastFocus B.V.
Gerverscop 9
3481 LT Harmelen
The Netherlands