

Certificate

Certificate P000536327CRT01



First issue 25-Aug-2020 by SGS Belgium NV Re-certification 11-Feb-2026
Reissued 01-Jan-2023 by Kiwa Dare B.V. Technical Area 1.2
Valid until 11-Feb-2029

Quality Management System Certificate EN-ISO 13485:2016

For the Quality Management System of

FastFocus B.V.

Regarding the scope Design, development, manufacture, service and distribution of noninvasive vital signs monitoring devices in the area of Institutional care.

This certificate is based on the following documents:
P000536327RPT01

Kiwa Assurance B.V. hereby declares that it has audited the quality management system in accordance with EN-ISO 13485:2016 + AC:2018 + A11:2021 and that all requirements of the standard and its implementation are fulfilled.

The certificate validity is three years and includes the surveillance obligations of EN-ISO/IEC 17021-1:2015.

DocuSigned by:
Natascha Cuper
6B5E3A6BE84046A...
Dr. N. Cuper
Certification Decision Maker

Signed by:
Dennis van der Vlugt
4F831C843C0B4EA...
Ing. D. Van der Vlugt
Director

This certificate consists of 2 page(s)
Disclosure of the certificate is permitted



Kiwa Assurance B.V. (Kiwa Medical Certification)
Vijzelmolenlaan 7
3447 GX Woerden
The Netherlands
T. +31 348 200 980
nl.nboffice@kiwa.com
www.kiwapid.eu

FastFocus B.V.
Gerverscop 9
3481 LT Harmelen
The Netherlands

Certificate

Appendix of EN-ISO 13485 Certificate



For the certificate P000536327CRT01

Revision history

Version	Changes
P000536327CRT01	Renewed certificate

The certificate P000536327CRT01

