



Doc No.: KF-CE-EN/2

Rev No.: 1.3

EC DECLARATION OF CONFORMITY

In accordance with the EU Parliament and Council Directive 93/42/CEE, concerning Medical Devices:

Manufacturer name : SAS KINVENT BIOMECAIQUE
 Manufacturer's address : Zac Eureka, Bâtiment Apollo A, 6 Rue de Pommessargues, 34000 Montpellier, France, Telephone: +33 411280695
 Manufacturer's SRN : FR-MF-000031884

Name	Model	Basic UDI-DI	GMDN NAME	GMDN Code	UMDNS Code
KForce Plates	K Force Plates	3770011995KPlatesD2	Biomechanical function analysis system, force-testing, portable	63456	17242
KForce Muscle Controller	K Push	3770011995KPushET	Back/leg/chest dynamometer, electronic	61672	17681
KForce Bubble	K Bubble	3770011995KBubble7M	Back/leg/chest dynamometer, electronic	61672	17681
KForce Grip	K Grip	3770011995KGripBX	Hand dynamometer / pinch meter, electronic	33785	17681
KForce Link	K Pull	3770011995KPullEE	Back/leg/chest dynamometer, electronic	61672	17681
KForce Sens	K Move	3770011995KMoveDB	Electronic goniometer/ kinesiology sensor	33652	13536
KForce Deltas	K Deltas	3770011995KDeltas7S	Biomechanical function analysis system, force-testing, portable	63456	17242
KForce Deltas	K Deltas XL	3770011995KDeltas7S	Biomechanical function analysis system, force-testing, portable	63456	17242

Intended Use : The K-Sensors are intended to be used by trained professionals to assist with objective assessment of a person's physical strength, balance, and range of motion.

Device Class and Rule : Class I, Rule 12 of Annex IX of Council Directive 93/42/EEC

We hereby declare, under our sole responsibility, that the product to which this declaration relates, is in conformity with the relevant provisions of standards and other normative document(s) and fulfils the general safety and performance requirements.

This declaration of conformity is issued under the sole responsibility of SAS KINVENT BIOMECAIQUE in compliance with Annexes VI & VII of Council Directive 93/42/CEE.

This declaration is based on:

(A) Harmonized Standards

EN ISO 14971 :2019, EN ISO 10993-1:2020, EN ISO 15223-1 :2021 EN 60601-1:2006/A1:2013, EN 60601-111 :2015/A1 :2021, EN 60601-1-2:2021, EN 62304:2006/A1 :2015, EN ISO 13485:2016, EN ISO 20417:2021.

(B) Technical File. ID Number: P-21 Medical Device File_V1R7, issued on 23.04.2024



Manufacturer : SAS KINVENT BIOMECAIQUE
Authorized Signatory & Designation : Athanase Kollias, CEO
Signature :

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DocuSigned by:

Athanase Kollias

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Place : Montpellier, France
Date : 31/01/2025