Number: 2265778CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Itémedical B.V.

De Ooyen 5A
4191 PB Geldermalsen
The Netherlands
SRN ID.: NL-MF-000010918

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 2148395CN

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation 2017/745.

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

F. Godeke
Principal Certification Manager

First Issued: **9 January 2024** Date: **7 September 2026** Expiry date**: 1 January 2029**

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DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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This certificate covers the following device(s) / groups of device(s):

Vital sign monitoring instruments (Z120302, class IIb)	
Device Name: MediScore MDDG	*Intended Purpose: MediScore Medical Device Data Gateway (MDDG) is a software system that forwards medical data from supported source devices to other devices operated by professional caregivers. Data may include vitals, settings, alarms, and other information. It has an information-oriented as well as an alarm-oriented use.*
Device Name: Itesuite	*Intended Purpose: Itesuite is a software system that forwards medical data from supported source devices to other devices operated by professional caregivers. Medical data may include vitals, settings, alarms, and other information. It has an information-oriented as well as an alarm-oriented use.* *In its information-oriented context, selected data is forwarded, e.g., to a clinical or hospital information system. This includes, but is not limited to, vitals and settings.* *The alarm-oriented context is a distributed alarm system (DAS), which may support acknowledgements for confirmed delivery (CDAS). Alarms are filtered, enhanced with medical-contextual information, and forwarded to a device operated by a professional caregiver. Amongst others, alarms involve the remote monitoring of vital physiological processes, e.g., cardiac performance and respiration. Filtering out irrelevant alarms, critical alarms will receive a faster response as a benefit.* *Itesuite consists of three configurable components: itegateway, itelogic, and itemobile.* *The required itegateway component communicates with source medical devices and receives medical data. It forwards medical data to either itelogic, itemobile, or an alternative Alarm Distribution System (ADS). If itelogic is not present, itegateway performs filtering. Further, itegateway can forward data to one or more information systems.*

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	The optional itelogic component has filtering possibilities for efficient alarm management and can act as an Intelligent Alarm System (IAS). It continuously analyzes parameters and device alarms. It may generate patient status indicators for the early recognition of physiological deterioration and prompt timely clinical assessment. Additionally, itelogic may escalate alarms when frequent subthreshold alarm conditions occur over time and may integrate multiple simultaneous alarm conditions into a single alarm signal. *The optional itemobile component addresses the distribution, redirection, and escalation of filtered medical events to a mobile communication device. The device presents alarms with visual, auditory, and vibratory alarm signals, having varying priority. Itesuite does not control the source medical device. It is supplementary and does not fully replace the primary audible and visual medical device alarms, which remain required in fallback scenarios. The offered functionality is always restricted to limitations imposed by the medical device's manufacturer.*

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Conditions for or limitations to the validity of this certificate:

- N/A

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of Issue certificate	Certification Notice Reference	Action
0	9 January 2024	2148395CN06	First issue
1	25 January 2024	2148395CN07	revised
2	7 September 2026	2148395CN10	revised

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