DECLARATION OF CONFORMITY

Manufacturer's Name: Maxtec, LLC
Address: 2305 South 1070 West
Salt Lake City, Utah 84119
USA

SRN: US-MF-000003961

European Representative: EMERGO EUROPE
Westervoortsedijk 60,
6827 AT Arnhem
The Netherlands
European Representative SRN: NL-AR-000000116

Basic UDI DI: 081777002Smartstack68

Product Name(s): SmartStack IV Stand Family

Part Number/ Identification
R100P49-001
R100P49-006
R100P49-010
R100P90
R100P90-001
R100P73
R100P74
R100P86

Intended Purpose: The SmartStack IV Stand and SmartStack Equipment Stand products are medical devices used to support intravenous supply bags and other medical equipment for patient treatment.

Risk Class & GMDN: Class I 36069 – Stand, Infusion

Classification Criteria: Clause 4.1 Rule 1 of Annex VIII EU MDR 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above mentioned products meet the provisions of the following EC Council Regulations,

Common Specifications and Standards. All supporting documents are retained under the premises of the manufacturer and the European Representative.

Regulations:	Medical Device Regulation 2017/745
Notified Body:	N/A
Conformity Assessment:	Annex II, Technical Documentation & Annex III, Technical Documentation on Post-Market Surveillance
EC Certificate No.:	Product is Self-Certified
Date CE mark was affixed:	20 November 2009

This Declaration is considered valid from the date of the signature below.

Issued by Signature: Ashwini Kadam Digitally signed by Ashwini Kadam Date: 2026.10.07 13:08:20 +05'30' Date: 07/10/2026

Name: Ashwini Kadam
Position: Regulatory Specialist

Approved by Signature: Rebecca Hudson Rebecca Hudson (Oct 8, 2026 14:18:43 EDT) Date: Oct 8, 2026

Name: Rebecca Hudson
Position: VP, Regulatory Affairs and Quality Assurance

This Declaration supersedes any preceding Declaration of Conformity for the SmartStack IV Stand Family.

Applied Common Specification and Standards:

The referenced list of Common Specifications and harmonized standards for which documented evidence of compliance can be provided includes:

EN ISO 13485:2016 (ISO 13485:2016)
EN ISO 14971:2019 (ISO 14971:2019)
BS EN ISO 20417:2021
EN ISO 15223-1:2021
IEC 60601-1:2005 + AMD1:2012/AMD2:2020

QR-0024 (21) SmartStack IV Pole

Final Audit Report 2026-10-08

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