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## 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

**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

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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:  Date: May 08, 2023

Name: Anvitha Anand Rao  
Position: Regulatory and Quality Product Engineering Specialist

Approved by Signature:  Date: May 08, 2023

Name: Sidra Hankins  
Position: VP of QA/RA

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 15223-1:2016 (ISO 15223-1:2016, Corrected Version 2017-03)  
EN ISO 10993-1:2009 (ISO 10993-1:2009)