

Declaration of EU Conformity

Document no./
Month / Year eg_polyMIT_NTC_E
 11/2020

Manufacturer: Sedlbauer Aktiengesellschaft

Address: Wilhelm - Sedlbauer - Straße 2
 94481 Grafenau

Product Description: **Medical isolation transformer polyMIT®
polytronik® Medical Isolating Transformer**

polyMIT® 350
polyMIT® 700
polyMIT® 1000
polyMIT® 1700

item number: 312900-01
item number: 312900-02
item number: 312900-03
item number: 312900-04

The above mentioned products are in accordance with the following European directives:

Number: Medical Device Regulation No. 2017/745
 class I according to annex VIII, chapter III, rule 1

Text: Regulation (EU) 2017/745 of the European parliament and of the council on medical devices

The conformity of the mentioned products with the directive MDR 2017/745 is verified by the complete compliance with the following standards:

DIN EN 61558-1; VDE 0570-1:2019-12
DIN EN 61558-2-4; VDE 0570-2-4: 2009-12
IEC 60601-1:2013-12 / EN 60601-1-2:2015

Issued by: Sedlbauer AG
 Wilhelm - Sedlbauer - Straße 2
 94481 Grafenau

Place, Date: Grafenau, November 16th 2020

Legally binding
signature:

.....
Tobias Feilmeier, CEO

 **SEDLBAUER AG**
Elektromechanik – Gerätee Bau – Elektronik – Telekommunikation
Wilhelm-Sedlbauer-Straße 2
94481 GRAFENAU · DEUTSCHLAND

Sedlbauer AG is solely responsible for the creation of this EU declaration of conformity.

This declaration certifies the compliance with the mentioned directives but does not include any warranty of features.

Declaration of EU Conformity

Document no./
Month / Year eg_polyMIT_E
 11/2020

Manufacturer: Sedlbauer Aktiengesellschaft

Address: Wilhelm - Sedlbauer - Straße 2
 94481 Grafenau

Product Description: **Medical isolation transformer polyMIT®
polytronik® Medical Isolating Transformer**

polyMIT® 350e	item number: 312901-01
polyMIT® 700e	item number: 312901-02
polyMIT® 1000e	item number: 312901-03
polyMIT® 1700e	item number: 312901-04

The above mentioned products are in accordance with the following European directives:

Number: Medical Device Regulation No. 2017/745
 class I according to annex VIII, chapter III, rule 1

Text: Regulation (EU) 2017/745 of the European parliament and of the
 council on medical devices

The conformity of the mentioned products with the directive MDR 2017/745 is verified by the complete compliance with the following standards:

DIN EN 61558-1; VDE 0570-1:2019-12
DIN EN 61558-2-4; VDE 0570-2-4: 2009-12
IEC 60601-1:2013-12

Issued by: Sedlbauer AG
 Wilhelm - Sedlbauer - Straße 2
 94481 Grafenau

Place, Date: Grafenau, November 16th 2020

Legally binding
signature:

.....
Tobias Feilmeier, CEO

 **SED LBAUER AG**
Elektromechnik – Gerätebau – Elektronik – Telekommunikation

Wilhelm-Sedlbauer-Straße 2
94481 GRAFENAU · DEUTSCHLAND

Sedlbauer AG is solely responsible for the creation of this EU declaration of conformity.

This declaration certifies the compliance with the mentioned directives but does not include any warranty of features.