

## Konformitätserklärung Declaration of Conformity

Wir

We

**B. Braun Melsungen AG**  
**Carl-Braun-Straße 1**  
**34212 Melsungen**  
**Deutschland/Germany**  
**SRN DE-MF-000000201**

erklären in eigener Verantwortung,  
dass das Produkt

**Drug Library Manager Space<sup>plus</sup>**  
Softwareanwendung zur Verwaltung von  
Infusionspumpendaten  
Basis UDI-DI: 403923900000169539  
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte  
Verordnung (EU) 2017/745 übereinstimmt

**Konformitätsbewertungsverfahren**  
nach Anhang IX  
der oben genannten Verordnung

**Klassifizierung**  
gemäß Anhang VIII der oben genannten  
Verordnung  
Klasse IIb

**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123

**Gültig bis**  
gemäß gültigem EU Zertifikat  
G10 012974 0611

hereby declare in our own responsibility  
that the product

**Drug Library Manager Space<sup>plus</sup>**  
Software application to manage infusion  
pump information  
Basic UDI-DI: 403923900000169539  
(article numbers see Attachment I)

is in conformity with the requirements of the  
Medical Device Regulation (EU) 2017/745

**Conformity Assessment Procedure**  
according to annex IX  
of the Regulation named above

**Classification**  
according to annex VIII of the Regulation  
named above  
Class IIb

**Notified Body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123

**Valid until**  
according to our valid EU Certificate  
G10 012974 0611

**Anlage I / Attachment I****Basic UDI-DI 403923900000169539**

| <b>Art.-Nr. / Art. No.</b> | <b>Produktname / Product name</b>                                | <b>Klasse / Class</b> |
|----------------------------|------------------------------------------------------------------|-----------------------|
| 876203                     | Drug Library Manager Space <sup>plus</sup> (stand-alone version) | IIb                   |
| 876209                     | Drug Library Manager Space <sup>plus</sup> (platform version)    | IIb                   |

### Amendment Information

| Version | Description of the changes                                                                      |
|---------|-------------------------------------------------------------------------------------------------|
| 1.0     | Initial version of document.                                                                    |
| 2.0     | Amendment of article code 876209 Drug Library Manager Space <sup>plus</sup> (platform version). |

Title: Declaration of Conformity - 178-101 - Drug Library Manager Spaceplus - MDR Initiator: Malte Loh

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Loh, Malte (lohmatde)  
Title: HC-RA-DE08 Senior Manager Regulatory Affairs  
Date: Monday, 24 October 2022, 15:58 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Arico, Mareike (sommrde)  
Title: Head of QM active MD/ Head of Regulatory Affairs CoE AIS  
Date: Tuesday, 25 October 2022, 08:46 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Heil, Juergen (heiljrde)  
Title: VP Quality Management HC  
Date: Thursday, 27 October 2022, 09:20 W. Europe Daylight Time  
Meaning: Approve Document  
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