

Příloha č. 3



Odběratel:

KN Zlín

Dodavatel:

Johnson & Johnson, s.r.o.  
Wallerovo náměstí 329/1  
Praha 5, Jinonice, 158 00

Dne 20.06.2025  
Platnost 20.07.2025

UNIUM - Servisní Balík

|                |            |
|----------------|------------|
| Základ DPH 12% | 0,00       |
| Základ DPH 21% | 160 430,00 |

|         |           |
|---------|-----------|
| DPH 12% | 0,00      |
| DPH 21% | 33 690,30 |

|               |            |
|---------------|------------|
| Hodnota zboží | 160 430,00 |
| Celkem s DPH  | 194 120,30 |

| Popis | Obj. č.    | Název                                                | Ks | DPH | Ceniková cena bx | Sleva  | Cena bx    | Celková cena |
|-------|------------|------------------------------------------------------|----|-----|------------------|--------|------------|--------------|
| 00010 | VKPACKETCU | Servisní balík CU 05.001.601, 05.001.602, 05.001.604 | 1  | 21% | 181 399,00       | 11,56% | 160 430,00 | 160 430,00   |

Na balíček se vztahuje záruka 24. měsíců

Obsah servisního balíku:

05.001.601

Modulární rukojer UNIUM™

1ks

05.001.602

Náplječ jednotka UNIUM™ Power Unit

1ks

05.001.604

Adaptér UNIUM™ pro UBC II

1ks



Příloha č. 4

|                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| English                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                 |
|  <b>DePuy Synthes</b><br><small>PART OF THE Johnson &amp; Johnson FAMILY OF COMPANIES</small> |                                                                                                                                                                                                                                                                                                                                 |
| <b>EU DECLARATION OF CONFORMITY</b>                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                 |
| Manufacturer's Name                                                                                                                                                            | Synthes GmbH                                                                                                                                                                                                                                                                                                                    |
| Manufacturer's Address                                                                                                                                                         | Eimattstrasse 3<br>4436 Oberdorf<br>Switzerland                                                                                                                                                                                                                                                                                 |
| Manufacturer's Single Registration Number (SRN)                                                                                                                                | CH-MF-000013345                                                                                                                                                                                                                                                                                                                 |
| Authorised Representative's Name and Address                                                                                                                                   | DePuy Ireland UC<br>Loughbeg Ringaskiddy,<br>P43 ED82 Co. Cork,<br>IRELAND                                                                                                                                                                                                                                                      |
| Authorised Representative's Single Registration Number (SRN)                                                                                                                   | IE-AR-000009328                                                                                                                                                                                                                                                                                                                 |
| Technical Documentation Number                                                                                                                                                 | TF10657                                                                                                                                                                                                                                                                                                                         |
| Product and Trade Name(s)                                                                                                                                                      | Universal Battery Charger II                                                                                                                                                                                                                                                                                                    |
| Product Code(s)/Product Range and Description                                                                                                                                  | Refer to Attachment 1                                                                                                                                                                                                                                                                                                           |
| Intended Purpose                                                                                                                                                               | The Universal Battery Charger II is intended for charging and/or conditioning of authorized Batteries, Power Module and Power Unit.                                                                                                                                                                                             |
| Classification                                                                                                                                                                 | Refer to Attachment 1                                                                                                                                                                                                                                                                                                           |
| GMDN Code                                                                                                                                                                      | Refer to Attachment 1                                                                                                                                                                                                                                                                                                           |
| EMDN Code                                                                                                                                                                      | Z12130580                                                                                                                                                                                                                                                                                                                       |
| Basic UDI-DI value                                                                                                                                                             | Refer to Attachment 1                                                                                                                                                                                                                                                                                                           |
| RoHS                                                                                                                                                                           | <b>TF10127</b><br>We, Synthes GmbH (Eimattstrasse 3, CH-4436 Oberdorf), hereby declare the above listed Medical Device(s) complies with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. |
| <b>EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.</b>                                                                               |                                                                                                                                                                                                                                                                                                                                 |
| We, Synthes GmbH (Eimattstrasse 3, CH-4436 Oberdorf), hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.                 |                                                                                                                                                                                                                                                                                                                                 |

|                                      |                        |                                  |
|--------------------------------------|------------------------|----------------------------------|
| Document Number: 0000291032          | Version: see Windchill | Lifecycle State: <b>Approved</b> |
| Template: 103478875, Rev E, CR 22027 |                        | Reference: W-C-S050              |

# ATTACHMENT 1

|                                                                                                                                                                                   |              |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| <br><b>DePuySynthes</b><br><small>part of the Johnson &amp; Johnson family of companies</small> |              |
| <b>EU DECLARATION OF CONFORMITY</b>                                                                                                                                               |              |
| Manufacturer's Name                                                                                                                                                               | Synthes GmbH |
| Technical Documentation Number                                                                                                                                                    | TF10657      |

| LIST OF PRODUCT CODES/PRODUCTS RANGE |                              |                               |           |                    |
|--------------------------------------|------------------------------|-------------------------------|-----------|--------------------|
| Product Code                         | Product Description          | Classification                | GMDN Code | Basic UDI-DI value |
| 05.001.204                           | Universal Battery Charger II | Class I (Annex VIII, Rule 13) | 17115     | 7611819a000008HY   |
| 05.001.604                           | UNIUM™ Adapter f/UBC II      | Class I (Annex VIII, Rule 1)  | 60447     | 7611819a000008HY   |

|                                      |                        |                           |
|--------------------------------------|------------------------|---------------------------|
| Document Number: 000291032           | Version: see Windchill | Lifecycle State: Approved |
| Template: 103478875, Rev E, CR 22027 |                        | Reference: W-C-S050       |

| SIGNATURE SECTION |                                                                                                                           |      |                                         |
|-------------------|---------------------------------------------------------------------------------------------------------------------------|------|-----------------------------------------|
| Place of Issue    | Refer to Manufacturer's Address above                                                                                     |      |                                         |
| Signature         |                                                                                                                           | Date | Refer to date from electronic signature |
| Name/Title        | Amanda Vella Ivan (Senior Regulatory Affairs Manager Power Tools)                                                         |      |                                         |
| Signature         |                                                                                                                           | Date | Refer to date from electronic signature |
| Name/Title        | Christian Abel (Senior Quality Engineering Manager)<br><b>Manufacturer's Person Responsible for Regulatory Compliance</b> |      |                                         |

Note: The English DoC is considered the "EN Master DoC". The signatures with date in the "EN Master DoC" represent at the same time the validity for the translated DoCs.

[DoC Identifier: TF10657 PWT]

|                                     |                        |                           |
|-------------------------------------|------------------------|---------------------------|
| Document Number: 0000291032         | Version: see Windchill | Lifecycle State: Approved |
| Template:103478875, Rev E, CR 22027 |                        | Reference: W-C-S050       |



# MDR Declaration of Conformity



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                       |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| English                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                       |
| <p><b>EU DECLARATION OF CONFORMITY</b><br/>DoC Identifier: TF10668 PWT</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                       |
| Manufacturer's Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Synthes GmbH                                                                                                                                                                                                                                                                                                                                          |
| Manufacturer's Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Eimattstrasse 3<br>4436 Oberdorf<br>Switzerland                                                                                                                                                                                                                                                                                                       |
| Manufacturer's Single Registration Number (SRN)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | CH-MF-000013345                                                                                                                                                                                                                                                                                                                                       |
| Authorized Representative's Name and Address                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | DePuy Ireland UC<br>Loughbeg Ringaskiddy<br>P43 ED82 Co. Cork<br>Ireland                                                                                                                                                                                                                                                                              |
| Authorized Representative's Single Registration Number (SRN)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | IE-AR-000009328                                                                                                                                                                                                                                                                                                                                       |
| Notified Body Name                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | TÜV SÜD Product Service GmbH                                                                                                                                                                                                                                                                                                                          |
| Notified Body Identification Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 0123                                                                                                                                                                                                                                                                                                                                                  |
| Technical Documentation Number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | TF10668                                                                                                                                                                                                                                                                                                                                               |
| Product and Trade Name(s)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | UNIUM                                                                                                                                                                                                                                                                                                                                                 |
| Product Code(s)/Product Range and Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| Intended Purpose                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| Classification                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| GMDN Code                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| EMDN Code                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| Basic UDI-DI value                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Refer to Attachment 1                                                                                                                                                                                                                                                                                                                                 |
| Restriction of Hazardous Substances (RoHS) Directive                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <p>RoHS Technical File TF10127.</p> <p>We, Synthes GmbH (Eimattstrasse 3, CH-4436 Oberdorf), hereby declare the above listed Medical Device(s) complies with the European Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.</p> |
| <p><b>This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.</b><br/>         We, Synthes GmbH (Eimattstrasse 3, CH-4436 Oberdorf), hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.<br/>         This declaration is made on the basis of:<br/>         EU Quality System Certificate Number G10 056032 0104, issued by the Notified Body stated above, in accordance with Annex IX, Chapters I and III of Medical Device Regulation (EU) 2017/745.</p> |                                                                                                                                                                                                                                                                                                                                                       |

|                             |                        |                           |
|-----------------------------|------------------------|---------------------------|
| Document Number: 0000311529 | Version: See Windchill | Lifecycle State: Released |
| Template: 103478875, Rev H  |                        | Reference: W-C-S050       |

## MDR Declaration of Conformity



| SIGNATURE SECTION |                                                                                                                     |      |                                         |
|-------------------|---------------------------------------------------------------------------------------------------------------------|------|-----------------------------------------|
| Place of Issue    | Refer to Manufacturer's Address above                                                                               |      |                                         |
| Signature         |                                                                                                                     | Date | Refer to date from electronic signature |
| Name/Title        | Marie Ferrier<br>Regulatory Affairs Manager Power Tools                                                             |      |                                         |
| Signature         |                                                                                                                     | Date | Refer to date from electronic signature |
| Name/Title        | Christian Abel<br>Senior Quality Engineering Manager<br>Manufacturer's Person Responsible for Regulatory Compliance |      |                                         |

Note: The English DoC is considered the "EN Master DoC". The dated signature present in the "EN Master DoC" will represent the date of validity for any translated DoCs.

|                             |                        |                           |
|-----------------------------|------------------------|---------------------------|
| Document Number: 0000311529 | Version: See Windchill | Lifecycle State: Released |
| Template: 103478875, Rev H  |                        | Reference: W-C-S050       |

# MDR Declaration of Conformity



## ATTACHMENT 1

|                                                                        |              |
|------------------------------------------------------------------------|--------------|
| <br><b>EU DECLARATION OF CONFORMITY</b><br>DoC Identifier: TF10668 PWT |              |
| <b>Manufacturer's Name</b>                                             | Synthes GmbH |
| <b>Technical Documentation Number</b>                                  | TF10668      |

| Product Code | Product Description                | Intended Purpose                                                                                                                                                                                                                                                                | Classification    | GMDN Code | EMDN Code | Basic UDI-DI value |
|--------------|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------|-----------|--------------------|
| 05.001.601   | UNIUM™ Modular Handpiece           | The UNIUM Modular Handpiece is intended for drilling, reaming, burring, screwing, tapping and sawing bone and other bone-related tissue during traumatology and orthopedic surgeries. It is also intended for the placement of screws, wires, pins, and other fixation devices. | Class IIa, Rule 9 | 33541     | Z12130501 | 7611819a00731JW    |
| 05.001.602   | UNIUM™ Power Unit                  | The UNIUM Power Unit is intended to supply electrical energy to power the compatible handpieces. The power unit is a rechargeable unit and is intended to be inserted into the compatible handpieces.                                                                           | Class I, Rule 13  | 36534     | Z12130580 | 7611819a00732JY    |
| 05.001.603   | UNIUM™ Sterile Cover               | The UNIUM Sterile Cover is intended to ensure aseptic conditions when inserting the compatible non-sterile power unit into the compatible sterile handpieces.                                                                                                                   | Class I, Rule 1   | 47867     | Z12130580 | 7611819a00733K2    |
| 05.001.611   | UNIUM™ Reciprocating Saw Handpiece | The UNIUM Reciprocating Saw Handpiece is intended for sawing bone during traumatology and orthopedic surgeries. It can be used in conjunction with                                                                                                                              | Class IIa, Rule 9 | 66243     | Z12130501 | 7611819a00734K4    |

|                             |                        |                           |
|-----------------------------|------------------------|---------------------------|
| Document Number: 0000311529 | Version: See Windchill | Lifecycle State: Released |
| Template: 103478875, Rev H  |                        | Reference: W-C-S050       |

## MDR Declaration of Conformity



|            |                                                    |                                                                                                                                                                                 |                   |       |           |                 |
|------------|----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-------|-----------|-----------------|
|            |                                                    | the UNIUM Top for sternum when used for primary sternotomies.                                                                                                                   |                   |       |           |                 |
| 05.001.612 | UNIUM™ Top f/Sternum f/Reciprocating Saw Handpiece | The UNIUM Top for Sternum is intended to be used with the compatible handpieces to protect soft tissue from coming into contact with the saw blade during primary sternotomies. | Class IIa, Rule 6 | 44981 | Z12130580 | 7611819a00735K6 |

|                             |                        |                           |
|-----------------------------|------------------------|---------------------------|
| Document Number: 0000311529 | Version: See Windchill | Lifecycle State: Released |
| Template: 103478875, Rev H  |                        | Reference: W-C-S050       |



Příloha č. 6



9. ledna 2023

Všem dotčeným:

Synthes GmbH, se sídlem na adrese Eimattstrasse 3, 4436 Oberdorf, Švýcarsko, tímto prohlašuje, že instruktáž (jak je definována v českém zákoně o zdravotnických prostředcích) se nevyžaduje, a proto ji Synthes GmbH nezajišťuje.

Podle nařízení Evropského parlamentu a Rady EU 2017/745 ze dne 5. dubna 2017 o zdravotnických prostředcích Synthes GmbH poskytuje návod k použití, který splňuje požadavky stanovené v příloze I kapitoly 3 (požadavky týkající se informací poskytovaných spolu s prostředkem) a průvodce chirurgickou technikou jako doprovodné informace a nezajišťuje konkrétní školení pro koncového uživatele.

Kromě toho jsou naše zdravotnické prostředky určeny pro použití kvalifikovanými zdravotnickými pracovníky, např. chirurgy, lékaři, personálem na operačním sále a jednotlivci zapojenými do přípravy prostředku. Veškerý personál manipulující s prostředky by se měl řídit návodem k použití a průvodcem chirurgickou technikou, chirurgickými postupy, pokud se uplatňují, a/nebo brožurou s důležitými informacemi od společnosti Synthes.

Implantace se provádí podle návodu k použití v souladu s doporučeným chirurgickým postupem. Za vhodnost prostředku pro indikovanou diagnózu/nemoc a řádné provedení chirurgického zákroku nese odpovědnost chirurg.

S pozdravem

Jménem spol. Synthes GmbH

manazer RA pro strategické trhy a zdraví  
zvířat

Zástupce ředitele RA TECA  
Provádění, udržování a řízení  
procesů MDR

