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| <br><b>LEONHARD LANG</b> | <b>Konformitätserklärung VO (EU)</b><br><b>2017/745 EKG-Elektroden Skintact</b><br><i>Declaration of Conformity REG (EU) 2017/745 ECG</i><br><i>Electrodes Skintact</i> | Dok.Nr. 10062541    Rev. C<br>Bereich KONFORMITÄTSERKLÄRUNG<br>Klasse EKG Elektroden<br>Seite 1 / 5 |
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**EG-KONFORMITÄTSERKLÄRUNG**  
**EC DECLARATION OF CONFORMITY**  
**DECLARATION DE CONFORMITE CE**

**Hersteller / Manufacturer / Fabricant**

|                                                                                                                     |                                              |
|---------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Name / Name / Nom                                                                                                   | <b>Leonhard Lang GmbH</b>                    |
| Adresse / Address / Adresse                                                                                         | <b>Archenweg 56, 6020 Innsbruck, Austria</b> |
| <b>Single Registration Number /</b><br><i>Single Registration Number /</i><br><i>Numéro d'enregistrement unique</i> | <b>AT-MF-000000426</b>                       |

**Produkte / Products / Produits**

|                                              |                        |
|----------------------------------------------|------------------------|
| Produktname                                  | <b>EKG-Elektroden</b>  |
| <i>Product name</i>                          | <i>ECG Electrodes</i>  |
| <i>Nom du produit</i>                        | <i>Électrodes ECG</i>  |
| Basis-UDI-DI / Basic UDI-DI / IUD-ID de base | 9005531ECGElectrodesCM |

**Verfahren nach / Procedure of / Procédure**

|                          |                            |
|--------------------------|----------------------------|
| VO (EU) 2017/745         | <b>Anhang II &amp; III</b> |
| <i>REG (EU) 2017/745</i> | <i>Annex II &amp; III</i>  |
| <i>RÈG (UE) 2017/745</i> | <i>Annexe II &amp; III</i> |

**Klassifizierung nach / Classification according / Classification conformément à**

|                                       |                                           |
|---------------------------------------|-------------------------------------------|
| VO (EU) 2017/745, Anhang VIII         | <b>Klasse I nach Regel 1</b>              |
| <i>REG (EU) 2017/745, annex VIII</i>  | <i>Class I according Rule 1</i>           |
| <i>RÈG (UE) 2017/745, annexe VIII</i> | <i>Classe I conformément à la règle 1</i> |

Leonhard Lang GmbH erklärt in alleiniger Verantwortung, dass die Produkte in der gelieferten Ausführung den Anforderungen der Verordnung (EU) 2017/745 entsprechen. Die Produkte werden mit dem CE-Kennzeichen versehen.

*Leonhard Lang GmbH declares under sole responsibility that the products as delivered are in compliance with regulation (EU) 2017/745. The products are CE marked.*

*Leonhard Lang GmbH déclare sous sa seule responsabilité que les produits de la version livrée sont conformes aux exigences du règlement (UE) 2017/745. Les produits reçoivent la marque CE.*



Innsbruck, 25.05.2021

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Burrhus Lang, CEO

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| <br><b>LEONHARD LANG</b> | <b>Konformitätserklärung VO (EU)</b><br><b>2017/745 EKG-Elektroden Skintact</b><br><i>Declaration of Conformity REG (EU) 2017/745 ECG</i><br><i>Electrodes Skintact</i> | Dok.Nr. 10062541      Rev. C<br>Bereich KONFORMITÄTSERKLÄRUNG<br>Klasse EKG Elektroden<br>Seite 2 / 5 |
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## Anhang: Artikelliste

Appendix: Article list

Annexe: liste d'articles

| Artikelnummer<br><i>Item number</i><br><i>Numéro d'article</i> | Produktname<br><i>Product name</i><br><i>Nom du produit</i> |                | Beutel<br><i>Pouch</i><br><i>Pochette</i> | Karton<br><i>Box</i><br><i>Carton</i> | Umkarton<br><i>Case</i><br><i>Caisse</i> |
|----------------------------------------------------------------|-------------------------------------------------------------|----------------|-------------------------------------------|---------------------------------------|------------------------------------------|
| 50003                                                          | SKINTACT                                                    | F-261          | 30                                        | 1500                                  | -                                        |
| 50049                                                          | SKINTACT                                                    | FS-VM01 -10    | 10                                        | 500                                   | 3000                                     |
| 50071                                                          | SKINTACT                                                    | RT34           | 100                                       | 500                                   | 5000                                     |
| 50099                                                          | SKINTACT                                                    | FS-VM01 -10    | 10                                        | 500                                   | 3000                                     |
| 50111                                                          | SKINTACT                                                    | FS-VM01        | 50                                        | 500                                   | 3000                                     |
| 50137                                                          | SKINTACT                                                    | FS-521 (L)     | 30                                        | 1500                                  | -                                        |
| 50254                                                          | SKINTACT                                                    | F-RG1          | 30                                        | 1500                                  | -                                        |
| 50256                                                          | SKINTACT                                                    | FS-VP01        | 50                                        | 500                                   | 3000                                     |
| 50283                                                          | SKINTACT                                                    | PD10-F4 /5 -10 | 10                                        | 150                                   | -                                        |
| 50289                                                          | SKINTACT                                                    | F-261          | 30                                        | 1500                                  | -                                        |
| 50302                                                          | SKINTACT                                                    | FS-WA10C       | 50                                        | 500                                   | 3000                                     |
| 50340                                                          | SKINTACT                                                    | PD-50SF        | 3                                         | 120                                   | -                                        |
| 50366                                                          | SKINTACT                                                    | FS-VM01 A1.5   | 50                                        | 500                                   | 3000                                     |
| 50374                                                          | SKINTACT                                                    | FS-WA00 /10    | 50                                        | 500                                   | 3000                                     |
| 50380                                                          | SKINTACT                                                    | FS-RB5 /5      | 50                                        | 1500                                  | -                                        |
| 50388                                                          | SKINTACT                                                    | FS-301         | 30                                        | 1500                                  | -                                        |
| 50407                                                          | SKINTACT                                                    | W-130C /3      | 30                                        | 1500                                  | -                                        |
| 50423                                                          | SKINTACT                                                    | PD50-SF (150)  | 3                                         | 150                                   | -                                        |
| 50425                                                          | SKINTACT                                                    | PD50-SFC       | 3                                         | 150                                   | -                                        |
| 50427                                                          | SKINTACT                                                    | PD50-F4C       | 3                                         | 150                                   | -                                        |
| 50428                                                          | SKINTACT                                                    | RT38           | 100                                       | 500                                   | 5000                                     |
| 50462                                                          | SKINTACT                                                    | FS-50C         | 30                                        | 300                                   | 1800                                     |
| 50493                                                          | SKINTACT                                                    | FS-TC1         | 30                                        | 1500                                  | -                                        |
| 50532                                                          | SKINTACT                                                    | FS-RGC /10     | 50                                        | 1500                                  | -                                        |
| 50533                                                          | SKINTACT                                                    | FS-TF1         | 30                                        | 1500                                  | -                                        |
| 50543                                                          | SKINTACT                                                    | FS-RB4 /5      | 50                                        | 1500                                  | -                                        |
| 50548                                                          | SKINTACT                                                    | T-VO01         | 30                                        | 300                                   | 1800                                     |
| 50574                                                          | SKITNACT                                                    | T-VO02         | 30                                        | 300                                   | 1800                                     |
| 50575                                                          | SKINTACT                                                    | FS-RG1 /10     | 50                                        | 1500                                  | -                                        |
| 50577                                                          | SKINTACT                                                    | FS-50          | 30                                        | 1200                                  | -                                        |
| 50583                                                          | SKINTACT                                                    | FS-TC1 /10     | 50                                        | 1500                                  | -                                        |
| 50612                                                          | SKINTACT                                                    | FS-TF /6       | 30                                        | 1200                                  | -                                        |
| 50631                                                          | SKINTACT                                                    | FS-RG1 /10     | 50                                        | 1500                                  | -                                        |
| 50635                                                          | SKINTACT                                                    | FS-RG1         | 50                                        | 1500                                  | -                                        |
| 50664                                                          | SKINTACT                                                    | F-VK04         | 30                                        | 750                                   | -                                        |

| Artikelnummer<br><i>Item number</i><br><i>Numéro d'article</i> | Produktname<br><i>Product name</i><br><i>Nom du produit</i> |             | Beutel<br><i>Pouch</i><br><i>Pochette</i> | Karton<br><i>Box</i><br><i>Carton</i> | Umkarton<br><i>Case</i><br><i>Caisse</i> |
|----------------------------------------------------------------|-------------------------------------------------------------|-------------|-------------------------------------------|---------------------------------------|------------------------------------------|
| 50672                                                          | SKINTACT                                                    | F-50C /3 -3 | 3                                         | 600                                   | 2400                                     |
| 50779                                                          | SKINTACT                                                    | F-601 /5 -5 | 5                                         | 600                                   | --                                       |
| 50790                                                          | SKINTACT                                                    | RT58        | 100                                       | 500                                   | 5000                                     |
| 50791                                                          | SKINTACT                                                    | RT59        | 100                                       | 500                                   | 5000                                     |
| 50811                                                          | SKINTACT                                                    | W-60 /50811 | 30                                        | 300                                   | 1800                                     |
| 50820                                                          | SKINTACT                                                    | F-301       | 30                                        | 1500                                  | -                                        |
| 50836                                                          | SKINTACT                                                    | FS-TC1C     | 30                                        | 1500                                  | -                                        |
| 50837                                                          | SKINTACT                                                    | FS-RG1 /6   | 30                                        | 1500                                  | -                                        |
| 50848                                                          | SKINTACT                                                    | F-55        | 30                                        | 1200                                  | -                                        |
| 50849                                                          | SKINTACT                                                    | FS-50       | 30                                        | 1200                                  | -                                        |
| 50850                                                          | SKINTACT                                                    | W-601       | 30                                        | 1500                                  | -                                        |
| 58001                                                          | SKINTACT                                                    | 24:00F /3   | 30                                        | 1200                                  | -                                        |
| 58002                                                          | SKINTACT                                                    | CT-50       | 30                                        | 1200                                  | 4800                                     |
| 58003                                                          | SKINTACT                                                    | CT-601      | 30                                        | 1500                                  | -                                        |
| 58008                                                          | SKINTACT                                                    | F-301       | 30                                        | 1500                                  | -                                        |
| 58009                                                          | SKINTACT                                                    | F-40        | 30                                        | 1200                                  | -                                        |
| 58014                                                          | SKINTACT                                                    | F-401       | 30                                        | 1500                                  | -                                        |
| 58016                                                          | SKINTACT                                                    | F-50        | 30                                        | 1200                                  | -                                        |
| 58017                                                          | SKINTACT                                                    | F-521       | 30                                        | 1500                                  | -                                        |
| 58018                                                          | SKINTACT                                                    | F-55        | 30                                        | 1200                                  | -                                        |
| 58021                                                          | SKINTACT                                                    | F-601       | 30                                        | 1500                                  | -                                        |
| 58025                                                          | SKINTACT                                                    | FS-321      | 30                                        | 1500                                  | -                                        |
| 58026                                                          | SKINTACT                                                    | FS-40       | 30                                        | 1200                                  | 4800                                     |
| 58027                                                          | SKINTACT                                                    | FS-401      | 30                                        | 1500                                  | -                                        |
| 58028                                                          | SKINTACT                                                    | FS-50       | 30                                        | 1200                                  | -                                        |
| 58029                                                          | SKINTACT                                                    | FS-50C      | 30                                        | 1200                                  | -                                        |
| 58030                                                          | SKINTACT                                                    | FS-501      | 30                                        | 1500                                  | -                                        |
| 58031                                                          | SKINTACT                                                    | FS-521      | 30                                        | 1500                                  | -                                        |
| 58033                                                          | SKINTACT                                                    | FS-601      | 30                                        | 1500                                  | -                                        |
| 58045                                                          | SKINTACT                                                    | T-401       | 30                                        | 1500                                  | -                                        |
| 58046                                                          | SKINTACT                                                    | T-60        | 30                                        | 1200                                  | -                                        |
| 58047                                                          | SKINTACT                                                    | T-601       | 30                                        | 1500                                  | -                                        |
| 58049                                                          | SKINTACT                                                    | W-401       | 30                                        | 1500                                  | -                                        |
| 58052                                                          | SKINTACT                                                    | W-601       | 30                                        | 1500                                  | -                                        |
| 58226                                                          | SKINTACT                                                    | F-60        | 30                                        | 1200                                  | 4800                                     |
| 58349                                                          | SKINTACT                                                    | F-50C       | 30                                        | 1200                                  | -                                        |
| 58438                                                          | SKINTACT                                                    | F-40C       | 30                                        | 1200                                  | -                                        |
| 58453                                                          | SKINTACT                                                    | FS-TB       | 30                                        | 1200                                  | 4800                                     |

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|----------------------------------------------------------------|-------------------------------------------------------------|--------------|-------------------------------------------|---------------------------------------|------------------------------------------|
| 58586                                                          | SKINTACT                                                    | RT41         | 100                                       | 500                                   | 5000                                     |
| 58634                                                          | SKINTACT                                                    | W-551        | 30                                        | 1500                                  | -                                        |
| 58643                                                          | SKINTACT                                                    | FS-VB01      | 30                                        | 1200                                  | -                                        |
| 58656                                                          | SKINTACT                                                    | RT24         | 100                                       | 1000                                  | 4000                                     |
| 58659                                                          | SKINTACT                                                    | RT41         | 100                                       | 1000                                  | 4000                                     |
| 58698                                                          | SKINTACT                                                    | CT-601       | 30                                        | 300                                   | 1800                                     |
| 58701                                                          | SKINTACT                                                    | F-301 CA     | 30                                        | 300                                   | 1800                                     |
| 58705                                                          | SKINTACT                                                    | F-TB         | 30                                        | 300                                   | 1800                                     |
| 58706                                                          | SKINTACT                                                    | F-TB1        | 30                                        | 300                                   | 1800                                     |
| 58709                                                          | SKINTACT                                                    | FS-524       | 30                                        | 300                                   | 1800                                     |
| 58710                                                          | SKINTACT                                                    | FS-RB5 /5    | 30                                        | 300                                   | 1800                                     |
| 58711                                                          | SKINTACT                                                    | FS-TC1 /6    | 30                                        | 300                                   | 1800                                     |
| 58715                                                          | SKINTACT                                                    | W-602        | 30                                        | 300                                   | 1800                                     |
| 58717                                                          | SKINTACT                                                    | RT74         | 100                                       | 500                                   | 5000                                     |
| 58763                                                          | SKINTACT                                                    | FS-TB1       | 30                                        | 1500                                  | 6000                                     |
| 58784                                                          | SKINTACT                                                    | FS-VB011     | 30                                        | 300                                   | 1800                                     |
| 58793                                                          | SKINTACT                                                    | F-TB1        | 30                                        | 1500                                  | -                                        |
| 58863                                                          | SKINTACT                                                    | RT14         | 100                                       | 500                                   | 5000                                     |
| 58916                                                          | SKINTACT                                                    | F-301 DI     | 30                                        | 1500                                  | -                                        |
| 58940                                                          | SKINTACT                                                    | F-521        | 30                                        | 1500                                  | -                                        |
| 58942                                                          | SKINTACT                                                    | FS-521L      | 30                                        | 1500                                  | -                                        |
| 58988                                                          | SKINTACT                                                    | T-604 B      | 30                                        | 1200                                  | -                                        |
| 59093                                                          | SKINTACT                                                    | FS-VB04      | 30                                        | 750                                   | -                                        |
| 59140                                                          | SKINTACT                                                    | F-401C       | 30                                        | 1500                                  | -                                        |
| 59141                                                          | SKINTACT                                                    | F-601C       | 30                                        | 1500                                  | -                                        |
| 59199                                                          | SKINTACT                                                    | FS-TB /3 -3  | 3                                         | 600                                   | 2400                                     |
| 59202                                                          | SKINTACT                                                    | FS-TB1 /5 -5 | 5                                         | 600                                   | 2400                                     |
| 59203                                                          | SKINTACT                                                    | FS-RC /4 -4  | 4                                         | 600                                   | 2400                                     |
| 59326                                                          | SKINTACT                                                    | F-TB -3      | 3                                         | 300                                   | 1800                                     |
| 59357                                                          | SKINTACT                                                    | FS-TA        | 30                                        | 300                                   | 1800                                     |
| 59405                                                          | SKINTACT                                                    | F-RG1 /6     | 30                                        | 1500                                  | -                                        |
| 59407                                                          | SKINTACT                                                    | FS-TC1 /6    | 30                                        | 1500                                  | -                                        |
| 59478                                                          | SKINTACT                                                    | FS-VF01      | 50                                        | 500                                   | 3000                                     |
| 59517                                                          | SKINTACT                                                    | FS-VF01 -10  | 10                                        | 500                                   | 3000                                     |
| 59578                                                          | SKINTACT                                                    | F-RG /6      | 30                                        | 1200                                  | -                                        |
| 59616                                                          | SKINTACT                                                    | FS-TF /6     | 30                                        | 1200                                  | -                                        |
| 59637                                                          | SKINTACT                                                    | FS-RG1 /6    | 30                                        | 1500                                  | -                                        |
| 59644                                                          | SKINTACT                                                    | FS-VF01C     | 50                                        | 500                                   | 3000                                     |

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| 59650                                                          | SKINTACT                                                    | FS-TF /6        | 30                                        | 300                                   | 1800                                     |
| 59651                                                          | SKINTACT                                                    | F-TF /6         | 30                                        | 1200                                  | -                                        |
| 59659                                                          | SKINTACT                                                    | FS-RG /6        | 30                                        | 1200                                  | -                                        |
| 59664                                                          | SKINTACT                                                    | F-VK01          | 50                                        | 500                                   | 3000                                     |
| 59693                                                          | SKINTACT                                                    | FS-RE /6        | 30                                        | 1200                                  | -                                        |
| 59712                                                          | SKINTACT                                                    | FS-TC1/6 (1200) | 30                                        | 1200                                  | 4800                                     |
| 59719                                                          | SKINTACT                                                    | W-401 DU        | 30                                        | 300                                   | 1800                                     |
| 59723                                                          | SKINTACT                                                    | F-TC1 /6        | 30                                        | 1500                                  | -                                        |
| 59804                                                          | SKINTACT                                                    | FS-WB00 /10     | 100                                       | 500                                   | 3000                                     |
| 59882                                                          | SKINTACT                                                    | PD50-SFC        | 3                                         | 150                                   | -                                        |