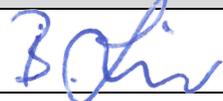


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| Document Type:      | DMR 03-001                            | Technical Documentation - SpiroTrue H |  |  |
|                     | Basic UDI-DI:                         | 42516796-001-WR                       |   |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |   |  |
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| Authored by: | Title/Position:                  | Date (YYYY-MM-DD):           | Signature:  |
|--------------|----------------------------------|------------------------------|---|
| N. Radev     | Dr.-Ing. / Project Leader        | 2022-05-17                   |  |
| Reviewed by: | Title/Position:                  | Date (YYYY-MM-DD):           | Signature:  |
| N. Radev     | Dr.-Ing. / PLV- Flow sensors     | 2022-05-17                   |  |
| B. Lindner   | Dipl.-Ing. / Head of R&D Dept.   | 2022-05-17                   |  |
|              |                                  |                              |   |
| Approved by: | Title/Position:                  | Effective Date (YYYY-MM-DD): | Signature:  |
| B. Lindner   | Dipl.-Ing. /General Manager/PRRC | 2022-07-01                   |  |

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|                     | Basic UDI-DI:                         | 42516796-001-WR                       |  |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |  |  |
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## 1. Purpose

The purpose of this document is to provide an overview of the revisions/change log of external documents, as labelling and packaging, for the product(s) mentioned that supports the Design Review Control (DRC) team by documents control.

## 2. Product data

| Product name | Product version | Product REF | UDI-DI (GTIN-14)  | Basic UDI-DI    |
|--------------|-----------------|-------------|-------------------|-----------------|
| SpiroTrue    | H               | 1030132000  | 2 42516796 0156 6 | 42516796-001-WR |

## 3. Product variants of SpiroTrue H as component for Manufactures of OEM Breathing Systems

| Product name | Product variant | Product REF | UDI-DI (GTIN-14)  | Basic UDI-DI    |
|--------------|-----------------|-------------|-------------------|-----------------|
| SpiroTrue    | H (2m)          | 4030131003  | 2 42516796 0163 4 | 42516796-001-WR |
| SpiroTrue    | D (2,2m)        | 6030131002  | 2 42516796 0165 8 | 42516796-001-WR |
| SpiroTrue    | D (3,2m)        | 6030131001  | 2 42516796 0164 1 | 42516796-001-WR |

## 4. Summary

The product specific requirements and applicable regulatory and safety standards related to the labelling and packaging are listed into Design Inputs SpiroTrue-H (Doc.ID Nr: BPM-DI-071112-001-NR-R4)

The labelling and packaging specifications had been updated, reviewed and approved by DRC team. The new/updated Labelling and Packaging (printed version) for the product(s) will REF to this document.

### Annex

Pictures of labelling and packaging for the product(s) and product variants listed into this document.

|            |  |            |
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|                     | Basic UDI-DI:                         | 42516796-001-WR                       |         |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |         |  |
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## 5. SpiroTrue H – REF 1030132000

### 5.1. Primary labelling 99x70mm (black/white), PE pouch 150x200mm (clear/nature)

**SpiroTrue® H**

single use flow sensor  
15M/15M with 2m sensor tube incl. hook and adaptor

**REF** 1030132000 **UDI** (01) 1 42516796 0156 9  
(11) 220101  
**LOT** 1234-5678-H **MD** (17) 250101  
(10) 1234-5678-H

1 pcs 2022-01-01 2025-01-01

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### 5.2. Secondary labelling 150x128mm, BOX FEFCO 0427 (235x165x105mm)

**SpiroTrue® H - single use flow sensor**

15M/15M with 2m sensor tube incl. hook and adaptor

|   |  |  |
|---|--|--|
| <b>de</b> Einweg- Flowsensor              | <b>cs</b> jednorázový průtokový senzor           | <b>ro</b> senzor de debit de unică folosință |
| <b>en</b> single use flow sensor          | <b>da</b> engangsstrømssensor                    | <b>et</b> ühekordselt kasutatav vooluandur   |
| <b>es</b> sensor de flujo de un solo uso  | <b>sv</b> engångsflödesgivare                    | <b>lv</b> vienreizējās plūsmas sensors       |
| <b>fr</b> capteur de débit à usage unique | <b>fi</b> kertakäyttöinen virtausanturi          | <b>lt</b> vienkartinis srauto jutiklis       |
| <b>it</b> sensore di flusso monouso       | <b>el</b> αισθητήρα ροής μιας χρήσης             | <b>ga</b> braiteoir sreabhadh indiciúscartha |
| <b>nl</b> wegwerp sensor                  | <b>hr</b> jednokratni senzor protoka             | <b>mt</b> sensor tal-fluss li jintremew      |
| <b>pl</b> jednorazowy czujnik przepływu   | <b>hu</b> eldobható áramlásérzékelő              | <b>ja</b> 使い捨て流量センサー                         |
| <b>pt</b> sensor de fluxo descartável     | <b>sk</b> jednorázový snímač prítoku             | <b>zh</b> 一次性流量傳感器                           |
| <b>ru</b> одноразовый датчик потока       | <b>sl</b> senzor pretoka za enkratno uporabo     |  |
| <b>tr</b> tek kullanımlık akış sensörü    | <b>bg</b> сензор за дебит за еднократна употреба |  |

50°C 95% 1060hPa  
-20°C 5% 700hPa

**REF** 1030132000 **LOT** 1234-5678-H 2022-01-01 **UDI** (01) 2 42516796 0156 6  
(11) 220101  
 6 pcs 2025-01-01 **MD** (17) 250101  
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| Document Type:      | DMR 03-001                            | Technical Documentation - SpiroTrue H |  |  |
|                     | Basic UDI-DI:                         | 42516796-001-WR                       |   |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |   |  |
| Document ID number: | BPM-LAP-080130-102-NR-R11             | Revision:                             | 11  |  |
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Pic.1: SpiroTrue H – REF 1030132000 (labelling and packaging)

|            |   |            |
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|                     | Basic UDI-DI:                         | 42516796-001-WR                       |  |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |  |  |
| Document ID number: | BPM-LAP-080130-102-NR-R11             | Revision:                             | 11   |  |
|                     |                                       | Status:                               | Release  |  |

## 6. SpiroTrue H with 2m tube – REF 4030131003

### 6.1. Primary labelling 99x70mm, PE Pouch 550x580mm (clear/nature)

**SpiroTrue® H** 

single use flow sensor  
15M/15M with 2m sensor tube  
Component for Manufacturers of OEM Breathing Systems

**REF** 4030131003 **UDI**  (01) 1 42516796 0163 7  
(11) 220101  
(17) 250101  
(10) 1234-5678-H

**LOT** 1234-5678-H **MD** 

 20 pcs  2022-01-01  2025-01-01

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Pic.2 : SpiroTrue H-REF 4030131003 (primary labelling and packaging)

|            |  |            |
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|                     | Basic UDI-DI:                         | 42516796-001-WR                       |         |  |
| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |         |  |
| Document ID number: | BPM-LAP-080130-102-NR-R11             | Revision:                             | 11      |  |
|                     |                                       | Status:                               | Release |  |

## 6.2. Secondary labelling 150x128mm, BOX FEFCO 2.7BC (850x380x410mm)

**SpiroTrue® H - single use flow sensor**

15M/15M with 2m sensor tube  
**Component for Manufacturers of OEM Breathing Systems**

|   |  |  |
|---|--|--|
| <b>de</b> Einweg- Flowsensor              | <b>cs</b> jednorázový průtokový senzor           | <b>ro</b> senzor de debit de unică folosință |
| <b>en</b> single use flow sensor          | <b>da</b> engangsstrømssensor                    | <b>et</b> ühekordselt kasutatav vooluandur   |
| <b>es</b> sensor de flujo de un solo uso  | <b>sv</b> engångsflödesgivare                    | <b>lv</b> vienreizējās plūsmas sensors       |
| <b>fr</b> capteur de débit à usage unique | <b>fi</b> kertäkäyttöinen virtausanturi          | <b>lt</b> vienkartinis srauto jutiklis       |
| <b>it</b> sensore di flusso monouso       | <b>el</b> αισθητήρα ροής μιας χρήσης             | <b>ga</b> braiteoir sreabhadh indíscartha    |
| <b>nl</b> wegwerp sensor                  | <b>hr</b> jednokratni senzor protoka             | <b>mt</b> sensor tal-fluss li jintremew      |
| <b>pl</b> jednorazowy czujnik przepływu   | <b>hu</b> eldobható áramlásérzékelő              | <b>ja</b> 使い捨て流量センサー                         |
| <b>pt</b> sensor de fluxo descartável     | <b>sk</b> jednorázový snímač prietoku            | <b>zh</b> 一次性流量傳感器                           |
| <b>ru</b> одноразовый датчик потока       | <b>sl</b> senzor pretoka za enkratno uporabo     |  |
| <b>tr</b> tek kullanımlık akış sensörü    | <b>bg</b> сензор за дебит за еднократна употреба |  |

**REF** 4030131003

**LOT** 1234-5678-H 2022-01-01 **UDI** (01) 2 42516796 0163 4  
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Pic.3 : SpiroTrue H-REF 4030131003 (secondary labelling and packaging)

|            |  |            |
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|                     | Basic UDI-DI:                         | 42516796-001-WR                       |  |  |
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| Document ID number: | BPM-LAP-080130-102-NR-R11             | Revision:                             | 11   |  |
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## 7. SpiroTrue D with 2,2m tube – REF 6030131002

### 7.1. Primary labelling 99x70mm, PE Pouch 550x580mm (clear/nature)

**SpiroTrue® D**  
single use flow sensor  
15M/15M with 2,2m sensor tube  
Component for Manufacturers of OEM Breathing Systems

**REF 6030131002**      **UDI**  (01) 1 42516796 0165 1  
**LOT 1234-5678-D**      **MD** (11) 220101  
(17) 250101  
(10) 1234-5678-D

 20 pcs       2022-01-01       2025-01-01

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Pic.4 : SpiroTrue D-REF 6030131002 (primary labelling and packaging)

|            |   |             |
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| Document name:      | SpiroTrue H – Labelling and Packaging |                                       |  |  |
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|                     |                                       | Status:                               | Release  |  |

## 7.2. Secondary labelling 150x128mm, BOX FEFCO 2.7BC (850x380x410mm)

**SpiroTrue® D - single use flow sensor**   
 15M/15M with 2,2m sensor tube  
**Component for Manufacturers of OEM Breathing Systems**

|   |  |  |
|---|--|--|
| <b>de</b> Einweg- Flowsensor              | <b>cs</b> jednorázový průtokový senzor           | <b>ro</b> senzor de debit de unică folosință |
| <b>en</b> single use flow sensor          | <b>da</b> engangsstrømssensor                    | <b>et</b> ühekordset kasutatav vooluandur    |
| <b>es</b> sensor de flujo de un solo uso  | <b>sv</b> engångsflödesgivare                    | <b>lv</b> vienreizējās plūsmas sensors       |
| <b>fr</b> capteur de débit à usage unique | <b>fi</b> kertakäyttöinen virtausanturi          | <b>it</b> vienkartinis srauto jutliklis      |
| <b>it</b> sensore di flusso monouso       | <b>el</b> αισθητήρα ροής μιας χρήσης             | <b>ga</b> braiteoir sreabhadh indiuscartha   |
| <b>nl</b> wegwerp sensor                  | <b>hr</b> jednokratni senzor protoka             | <b>mt</b> sensor tal-fluss li jintremew      |
| <b>pl</b> jednorazowy czujnik przepływu   | <b>hu</b> eldobható áramlásérzékelő              | <b>ja</b> 使い捨て流量センサー                         |
| <b>pt</b> sensor de fluxo descartável     | <b>sk</b> jednorázový snímač prietoku            | <b>zh</b> 一次性流量傳感器                           |
| <b>ru</b> одноразовый датчик потока       | <b>sl</b> senzor pretoka za enkratno uporabo     |  |
| <b>tr</b> tek kullanımlık akış sensörü    | <b>bg</b> сензор за дебит за еднократна употреба |  |



**REF** 6030131002

**LOT** 1234-5678-D  2022-01-01 **UDI**  (01) 2 42516796 0165 8  
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Pic.5 : SpiroTrue D-REF 6030131002 (secondary labelling and packaging)

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|                     |                                       | Status:                               | Release  |  |

## 8. SpiroTrue D with 3,2m tube – REF 6030131001

### 8.1. Primary labelling 99x70mm, PE Pouch 550x580mm (clear/nature)

**SpiroTrue® D**  
single use flow sensor  
15M/15M with 3,2m sensor tube  
Component for Manufacturers of OEM Breathing Systems

**REF** 6030131001      **UDI**  (01) 1 42516796 0164 4  
**LOT** 1234-5678-D      **MD** (11) 220101  
(17) 250101  
(10) 1234-5678-D

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Pic.6 : SpiroTrue D-REF 6030131001 (primary labelling and packaging)

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|                     |                                       | Status:                               | Release  |  |

## 8.2. Secondary labelling 150x128mm, BOX FEFCO 2.7BC (850x380x410mm)

**SpiroTrue® D - single use flow sensor**   
 15M/15M with 3,2m sensor tube  
**Component for Manufacturers of OEM Breathing Systems**

|   |  |  |
|---|--|--|
| <b>de</b> Einweg- Flowsensor              | <b>cs</b> jednorázový průtokový senzor           | <b>ro</b> senzor de debit de unică folosință |
| <b>en</b> single use flow sensor          | <b>da</b> engangsstrømssensor                    | <b>et</b> ühekordset kasutatav vooluandur    |
| <b>es</b> sensor de flujo de un solo uso  | <b>sv</b> engångsflödesgivare                    | <b>lv</b> vienreizējās plūsmas sensors       |
| <b>fr</b> capteur de débit à usage unique | <b>fi</b> kertakäyttöinen virtausanturi          | <b>lt</b> vienkartinis srauto jutiklis       |
| <b>it</b> sensore di flusso monouso       | <b>el</b> αισθητήρα ροής μίας χρήσης             | <b>ga</b> braiteoir sreabhadh indíscartha    |
| <b>nl</b> wegwerp sensor                  | <b>hr</b> jednokratni senzor protoka             | <b>mt</b> sensor tal-fluss li jintremew      |
| <b>pl</b> jednorazowy czujnik przepływu   | <b>hu</b> eldobható áramlásérzékelő              | <b>ja</b> 使い捨て流量センサー                         |
| <b>pt</b> sensor de fluxo descartável     | <b>sk</b> jednorázový snímač prietoku            | <b>zh</b> 一次性流量傳感器                           |
| <b>ru</b> одноразовый датчик потока       | <b>sl</b> senzor pretoka za enkratno uporabo     |  |
| <b>tr</b> tek kullanımlık akış sensörü    | <b>bg</b> сензор за дебит за еднократна употреба |  |



**REF** 6030131001

**LOT** 1234-5678-D  2022-01-01 **UDI**  (01) 2 42516796 0164 1  
 (11) 220101  
 (17) 250101  
 (10) 1234-5678-D

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Pic.2 : SpiroTrue D-REF 6030131001 (secondary labelling and packaging)

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|------------|---|-------------|
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