

PRODUCTION AND LICENSE AGREEMENT

This Agreement is made as of 2nd of April, 2024 (the “Effective Date”), by and between: **Microfluidic ChipShop GMBH** VAT-Nr.: DE 221812444, of Stockholmer Str. 20, 07745 Jena, Germany, Amtsgericht Jena: HRB 209251, Email: Claudia.Gaertner@microfluidic-ChipShop.com; contracts@microfluidic-ChipShop.com and **Mildendo Gesellschaft für mikrofluidische Systeme mbH** VAT-Nr. DE 206212271, of Sitz der Gesellschaft: 07745 Jena, Germany, Amtsgericht Jena: HRB 208260, Email: Claudia.Gaertner@microfluidic-ChipShop.com (together “**ChipShop**”), of the first part, and **DiagnosTear Ltd. Reg. No. 51-473376-5**, of Kiryat Atidim Building 7, 2nd Floor 61581 Tel Aviv, Israel, Email: shimon@diganostear.com; yaacov@bio-light.co.il (“**DiagnosTear**”), of the second part; (each of the above a “**Party**”, and collectively the “**Parties**”).

WHEREAS the Parties signed a development contract on 22.2.2016 (the “**2016 Contract**”) and amendments to the 2016 Contract (together: the “**Contract**”) according to which ChipShop granted DiagnosTear services of development and manufacture of a designated microfluid tear collector device according to DiagnosTear’s specific needs (the “**Tear Collector**” or the “**Product**”), and;

WHEREAS: The overall collaboration has been designed in a manner that microfluidic ChipShop will become the fabrication partner for the Tear Collector for DiagnosTear and has been willing to bring own efforts into this project. microfluidic ChipShop still wishes to become and remain the fabrication partner for DiagnosTear.

In order to give DiagnosTear the freedom to choose a fabrication partner different from microfluidic ChipShop, this license agreement has been compiled.

microfluidic ChipShop is still willing to bring own effort in this project to enable DiagnosTear the market entry.

Against this background, allowing DiagnosTear the freedom to choose a third party as manufacturer and microfluidic ChipShop in case of a change of supplier the compensation of effort, this License Agreement is set-up.

WHEREAS Following this Contract and respective amendment, the parties now agree on this Production and License Agreement (“**Agreement**”) according to which small-medium scale production of the Tear Collector will be manufactured by ChipShop and supplied to DiagnosTear. For large-scale manufacturing

DiagnosTear has the right to look for alternative supplier. In case DiagnosTear favors an alternative supplier, DiagnosTear will provide microfluidic ChipShop the quote and microfluidic ChipShop has the right to provide a competitive quote. In case that the competitive quote provided by microfluidic ChipShop will meet the prices from the alternative supplier, microfluidic ChipShop will have the right to fabricate.

WHEREAS It is agreed that the content of this Agreement will also define rights for DiagnosTear to use the patents and patent applications (summarized in **Exhibit A**) and the respective conditions for their use (together: the “**Patents**”).

WHEREAS the meaning of the following terms is defined as:

Field: Collection of tears directly from the eye

Product: Means the TearCollector consisting of a microstructured body, a cover film, a reagent storage blister, a cap and embedded dry reagents as further specified in Exhibit B.

To avoid any doubt, this Agreement covers design related topics only. Any fabrication and material related know-how from microfluidic ChipShop is excluded from this Agreement and will not be shared with DiagnosTear or licensed to DiagnosTear.

NOW, THEREFORE, the Parties hereby agree as follows:

1. “Small-Mid Scale” Production of the Tear Collector by ChipShop to DiagnosTear

1.1 “Small-Mid scale” means up to 100K per calendar year basis in a price in Euro per Tear Collector of up to [REDACTED] and respective price increases due to increases in wages, material, energy etc.. up to 5% p.a.

1.2 The Parties hereto agree that according to DiagnosTear needs, “Small-Mid Scale” Production of the Tear Collector shall be done by ChipShop.

The ordering procedure will be based on a quote from microfluidic ChipShop and an order from DiagnosTear. For 2024 the price is [REDACTED]

2. “Large Scale” Production of the Tear Collector to DiagnosTear and IP rights

2.1 “Large Scale” means any amount exceeding 100K Tear Collectors per calendar year.

2.2 The Parties agree that the Tear Collector in the exact designs provided to DiagnosTear is the sole property of DiagnosTear, however ChipShop has certain intellectual property

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due to
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sensitivity

covering some of the building blocks of the Tear Collector which are covered under the Patents detailed in Exhibit A

3. ChipShop hereby grants to DiagnosTear an exclusive worldwide royalty bearing license of the Patents, to the extent necessary to use the Patents for any Large Scale Production of the Product (Product always meaning the design for tear collection only, for all other applications DiagnosTear has no right to use the design and ChipShop is free to use the design), for the purpose of manufacturing, producing, marketing, selling, distributing the Products and/or practicing of the Products for the application of tear collection either by itself or through any third parties (the "License"). For the that purpose the Parties shall enter into a license agreement, on the basis, of the binding main terms attached to this Agreement as Exhibit C and constituting and integral part hereof.
4. The exclusivity of this license expires, if DiagnosTear does not generate an annual turnover with microfluidic ChipShop of ██████████ in the first year of production and ██████████ from the second year of production onwards.

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4.1 It is sole responsibility of DiagnosTear to ensure a freedom to operate for the respective product. ChipShop declares that it is to its best knowledge currently is not aware of any limitation on such Freedom to Operate.

5. ChipShop agrees not to develop, sell to or manufacture for any third party products that are used for tear collection and are based on patent family 1 referred to in Exhibit A and not to grant any third party any rights to exploit the Patents of patent family 1 listed in Exhibit A for the purpose of manufacturing any tear collecting applications ("Field") provided that DiagnosTear generates an annual turnover of minimum ██████████ in the first year following the effective date of this Agreement and ██████████ from the second year of onwards and the following years with microfluidic ChipShop. This paragraph does not refer to any of microfluidic ChipShop's standard & catalogue devices which might be used for application in the Field.

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This licence agreement does not include the use of the patents for any other product than the one shown in EXHIBIT B, e.g. a product using further building blocks and options included in the patents. Meaning, this license agreement is no waiver to a free use of the content of all design options of the patent families listed in this license agreement.

Should microfluidic ChipShop develop a new product for DiagnosTear embedding further building blocks covered within these patents, the same rules as defined for the PRODUCT will occur for those developments.

6. Chipshop represents and warrants that (i) it or its daughter company Mildendo Gesellschaft für mikrofluidische Systeme mbH is the sole and exclusive owner of the Patents / Patent applications

listed in Exhibit A, (ii) it has the right to grant the rights granted herein and the License, when granted, are and will be free and clear of any lien, encumbrances, security interest, (iii) it has not previously granted and will not grant any right, license or interest in and to the License in the Field, (iv) it has not previously granted and will not grant any right, license or interest in or to the Patents which contradicts the terms of this Agreement and/or restricts DiagnosTear from exploiting its rights hereunder, (v) there are no patents or other intellectual property owned or licensed by ChipShop that might be breached by the commercialization of the Tear Collector, except for the Patents, or if there should be would become part of this agreement and (vi) there are no threatened or pending actions, suits, investigations, claims or proceedings in any way relating to the License or the Patents up to date, (v) ChipShop is not responsible if these patents or the Product infringes any other patents and gives no freedom to operate clearance for DiagnosTear.

7. Ownership

7.1 Except for the Licenses expressly granted herein, nothing in this Agreement shall be construed to confer any ownership, interest, license, or other rights upon either party to any of the counter Party's know-how, technology, intellectual property, rights, products or materials. Further, nothing herein shall derogate from the ownership allocations specified in the Agreement.

7.2 Without derogating from the abovesaid, nothing in this Agreement will impair DiagnosTear's right to independently acquire, license, develop for itself, or have others develop for it, intellectual property and technology related to tear collecting applications or manufacture, market or distribute other products whatsoever including without limitation those based on such other intellectual property and technology.

8. No act or omission by any Party to this Agreement will entitle either Party to terminate or rescind the License granted hereunder.

9. Miscellaneous.

9.1 Governing Law and Dispute Resolution. This Agreement shall be governed by and interpreted under the laws of England and Wales without giving effect to the principles of conflict of laws thereunder. All disputes shall be referred to the appropriate court located in London, England.

9.2 Termination. This Agreement will automatically terminate and effect upon the earlier of (i) execution of Definitive LA (Licences Agreement) by the parties, (ii) mutual written agreement of the parties, (iii) on the date which is five years from the date of this Agreement (iv) Either party terminate it by written notice at least fourteen (14) days in advance or immediately upon a breach of this Agreement by the other party, which is not cured within

14 days after receipt of a notice regarding the breach. The provisions regarding Governing Law and Confidentiality, will survive the termination of this Agreement.

- 9.3 The Parties signed an NDA (Non-disclosure agreement) attached to this Agreement as **Exhibit H, which constitutes an integral part hereof.**
- 9.4 DiagnosTear may transfer, assign or endorse its rights pursuant to this Agreement to any third party without prior written consent of ChipShop. ChipShop may transfer, assign or endorse this Agreement provided that the License and rights granted to DiagnosTear hereunder remain intact. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the Parties and their successors and assigns.
- 9.5 Amendment; Waiver; Severability. This Agreement may be amended, modified, superseded or canceled, and any of the terms may be waived, only by a written instrument executed by both Parties. The delay or failure of any party at any time or times to require performance of any provisions hereof shall in no manner affect the rights at a later time to enforce the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be affected.
- 9.6 Notices. All notices under this Agreement shall be in writing and may be sent by certified mail, return receipt requested, to the address and mails detailed in the Preamble. Any notice shall be deemed to have been received: (i) by returned receipt email, one business day after transmission; (ii) by airmail, seven (7) business days after delivery to the postal authorities by the party giving notice.
- 9.7 Entire Agreement. This Agreement constitutes the full and complete agreement between the Parties with respect to the License and supersedes any and all agreements or understandings, whether written or oral, concerning the subject matter of this Agreement, if any, and may only be amended by a document signed by both Parties. Other than as set forth herein, the provisions of the Contract shall remain in full force and effect, insofar as it does not contradict the terms of this Agreement.

In witness whereof each of the Parties has signed this Agreement.

"Claudia Gärtner" (signed)

Jena, 22.06.2024

microfluidic ChipShop GmbH Claudia Gärtner

"Claudia Gärtner" (signed)

Jena, 22.06.2024

Mildendo Gesellschaft für Claudia Gärtner

mikrofluidische Systeme mbH

"Shimon Gross"

DiagnosTear Ltd.

"Yaacov Michlin"

Dr. Shimon Gross
CEO

DiagnosTear Ltd
Rehovot, Israel
23.06.2024

Yaacov Michlin
Chairman
DiagnosTear Ltd
Rehovot, Israel
23.6.2024

EXHIBIT A

List of Patent, Patent application and related proprietary know how

3 different patent families, which are covering building blocks relevant for the Diagnostear Tear Collector (patent family Nr. 1) or future products to be developed by microfluidic ChipShop on behalf of DiagnosTear (patent family 2 and 3).

1. DE102016122056B4: [DE] Mikrofluidisches System zur Aufnahme, Abgabe und Bewegung von Fluiden
2. DE102018111822B4 [DE] Fluidisches System zur Aufnahme, Abgabe und Bewegung von Flüssigkeiten, Verfahren zur Verarbeitung von Fluiden in einem fluidischen System
3. DE102018111834A1: Mikrofluidische Vorrichtung und Verfahren zur Nutzung derselben zur Trennung, Aufreinigung und Konzentration von Komponenten von fluidischen Medien,

EXHIBIT B

Main Terms of "Small-Mid Scale" Production of the Tear Collector by ChipShop and supplied to DiagnosTear

Unless otherwise specifically defined herein, all capitalized terms in this Exhibit B shall have the meaning ascribed to such terms under the Agreement to which this Exhibit is attached.

| | |
|---|---|
| Small-Mid Scale Production | up to 100K on a calendar annual basis |
| Product/Specifications | <p>Product shall be supplied to DiagnosTear in accordance with the specifications (EXHIBIT G) and agreed drawings of the Tear Collector detailed in Exhibit B1. In addition, it is agreed that in order to reduce the cost, the parties will make an effort that the Product design will be simplified.</p> <ul style="list-style-type: none"> • The first 10,000 devices will be produced in the current design, the following devices will be realized, material changes might occur not impacting the performance of the device. • The following deliveries will include design changes to be finalized preferably until end of December 2024. As a condition for implementing the new design, the parties will have to mutually agree on the changes. |
| Design/Equipment/Raw Material | <p>All costs with respect to manufacture and delivery of the Product (including without limitation further design required, investment (if required) for a production line, procurement of raw material and equipment etc. shall be borne exclusively by ChipShop. New designs / product concepts will be part of separate contracts and will be paid by DiagnosTear.</p> |
| Territory of Sale | Worldwide |
| Agreed Price | <p>██████████ each Product on <i>Ex-works</i> basis (Incoterms 2020), an annual price increase will occur according to the increase in general cost, wages and an inflation compensation and up to 5% p.a.</p> |
| Payment Terms | <p>Payment to ChipShop shall be made within 14 (fourteen) days from receipt by DiagnosTear of each batch of the Product, subject to receipt of a duly issued invoice from ChipShop.</p> |
| Purchase Order and Delivery Time | <p>For orders 1,000 to 4,999 pcs – up to 30 days For orders 5,000 to 9,999 pcs – up to 45 days For orders larger than 10,000 pcs – up to 60 days</p> |
| Shelf Life | <p>The residual shelf life of the Tear Guide hardware (dated from the acceptance date) should be no less than 24 months. Microfluidic ChipShop does not account for any responsibility for either shelf-life of reagents or damages occurring due to inappropriate shipping and storage.</p> |

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conditions. Expiry extension should be conducted in cooperation between the parties and according to real time stability analyses, risk assessments and production of the appropriate documentation according to the regulatory requirements.

The definition and responsibility for Shelf life of the reagents is sole responsibility of DiagnosTears.

The definition and responsibility for Shelf life of the hardware (e.g., attachment and assembly properties of the blister and film, other mechanical and hydraulic properties of the device) is sole responsibility of ChipShop.

Warranty Period/Repair & Replacement

Upon receipt of the Product by DiagnosTear, incoming QC analysis will be performed according to DiagnosTear Internal PMT-0041_Incoming Inspection Form [TearX chips]_Rev. 4 14-1-21 as included as Exhibit D. It is Agreed that DiagnosTear will conduct said QC inspections within up to 15 days from receipt of the Product. In the event that DiagnosTear will reject a certain Production batch/order, it will issue a written report to ChipShop within these 15 days, and will either return the Product (on Ex-Works basis, i.e., Freight, tax and insurance costs to be bared by ChipShop), or, as per the sole decision of ChipShop, dispose the rejected batch/order. Additionally, it is agreed that a replacement batch/order will be supplied by ChipShop according to the above lead times for supply on DDP (delivered duty paid) basis (incoterms 2020).

DiagnosTear may return any malfunctioning Product for repair or replacement free of charge during the applicable warranty period.

Should DiagnosTear's complaint be unjustified as evidenced by repeating the QC procedure defined in Exhibit E by microfluidic ChipShop or a third party or by identifying issues during transport, handling or storage after leaving microfluidic ChipShop premises, all cost that occurred due to the unjustified claim will be covered by DiagnosTears as well as that the payment for the parts delivered will be made by DiagnosTears.

Outsourcing

the Manufacturing can be outsourced by ChipShop (e.g. to associated companies)

Manufacturing authorizations /ChipShop Responsibility

ChipShop warrants that it possesses and shall continue to maintain throughout the term of this Agreement all required authorizations in order to manufacture the Product.

ChipShop declares that it is ISO13485 certified and that it will maintain this certification throughout the term of this Agreement.

ChipShop shall be solely responsible for carrying out the manufacturing of the Product according to ISO13485 standards. of. DiagnosTear will be in charge of all regulatory issues.

Without derogating from the generality of the above said, it is agreed that the QC process shall includethe following:

- (i) ChipShop’s QC testing procedures will be conducted according to the requirements of ISO 13485. Namely: QC release document (P-16-0116-TearGuide-FO-006 Messung Verdünnung Tropfengröße) will be duly signed by (1) the operator of the testing, and (2) by the QC/QA authorized authority/personnel.
- (ii) Chipshop’s QC procedure includes a visual inspection of the tip of the device being used for the tear collection (that comes in contact with the eye) in order to ensure that this part is smooth (avoiding damage to the eye).

Documentation and agreements that shall be annexed to the “Small-Mid Scale” Production of the Tear Collector by ChipShop to DiagnosTear

The following documentation shall be attached to each supplied Product batch

- (i) LOT-specific Certificate of Compliance (COC), Template attached as EXHIBIT E
- (ii) TeaRx Batch Record, TEMPLATE attached as EXHIBIT F ,
- (iii) invoice

The parties may change these documents commonly releasing the updated version / the replacement document.

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Fig. 1: Top-level design of the PRODUCT that will undergo some variations during the course of this Agreement (To be mutually agreed by the parties).

EXHIBIT C

Main Terms of Exclusive License Agreement

Unless otherwise specifically defined herein, all capitalized terms in this Exhibit C shall have the meaning ascribed to such terms under the Agreement to which this Exhibit is attached.

| | |
|---|--|
| Large Scale Production | any amount exceeding 100K Tear Collectors Per Calendar year. |
| <i>Licence/Product</i> | The licence covers the current Tear Collector Product as described in Exhibit B for the purpose of tear collection only and where its manufacturing, production or marketing is considered to be in violation of ChipShop's Patents listed in Exhibit A. The use of these patents for any other than this exact product is not part of this agreement. |
| "Licensed Patents" | The Patents detailed in Exhibit A |
| <i>Licensor</i> | ChipShop |
| <i>Licensee</i> | DiagnosTear it is agreed that DiagnosTear may sublicense the rights to manufacture, market, sale and distribute the Product at DiagnosTear sole discretion for no consideration to ChipShop. |
| <i>License in Large Scale Production</i> | ChipShop hereby grants to DiagnosTear an exclusive worldwide license under the Patents, to the extent necessary to use the Patents for any Large Scale Production of the Product, for the purpose of manufacturing, producing, marketing, selling, distributing the Products and/or practicing or making any other use (or any part of it) of the Products either by itself or through any third parties (the "License"). The License shall be worldwide and bearing royalties. The License covers the exact product only. The exclusivity directly expires if DiagnosTears does not meet the defined annual turnover as defined previously. The license also expires if annual turnovers are not met. |
| <i>Territory of License</i> | Worldwide |
| <i>Royalty and Term</i> | Royalty fee at the rate of [REDACTED] of the net cost price (the price DiagnosTear pays to the third Party for the manufacturing of the Product) until the earlier of: (i) accumulative net cost of Euro 0.5 million that shall be paid by DiagnosTear to Chipshop, or (ii) production of 5 million first Products ("Term"). After this, and only while DiagnosTear is granted an Exclusive License from Chipshop, the royalty will decrease to [REDACTED] DiagnosTear will supply respective documents summarizing |

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the Products purchased from Third Parties. On occasion ChipShop has the right by itself or an external auditor to review the purchasing and sales data (invoices, delivery notes) of the PRODUCT.

EXHIBIT D

Incoming Inspection Form – Visual and COA

DiagnosTear, Ltd.**In Coming Inspection Form I – Visual and COA****In Coming Inspection Form I**

| TearX Tear Collecting Chips | | | | |
|-----------------------------|-----------------|------------|----------|-----------|
| | Name | Title | Date | Signature |
| Revision No.: | RV4.0 | | | |
| Prepared by: | Dr. Amos Sommer | CCO | 14.01.21 | |
| Approved by: | Nissim Shaked | QA manager | 14.01.21 | |

Item Details:

| | | |
|--|---|-------------------|
| Item received: | TearX Tear Collector Disposable Chip | P/O Number: _____ |
| Item Category: (check one or two options) | Category I <input checked="" type="checkbox"/> Category II <input checked="" type="checkbox"/> | |

| Arrival Date | Diagnostear Cat No. | Manufacture Name | Manufacture Cat No. | Manufacture Lot No. | Quantity Ordered | Quantity received |
|--------------|------------------------|---------------------|------------------------|------------------------|---------------------|----------------------|
| | PMT-0041 | ChipShop | 30000348 | | | |

1. Category I Test**1.1. Inspection Record:**

| Inspection Type | Inspected Parameter | Results | Yes / No (Y / N) |
|--------------------------------------|---|---------|--|
| Visual Check (Mark "Yes" or "No") | Is the Item name / Cat No identical to P/O? | N/A | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | Is the Package uncompromised? | N/A | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | Is the delivery on time? | N/A | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| COA (Mark "Yes" or "No") | Tear Dilution Reproducibility | Passed | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | Droplet weight | Passed | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Physical check | Weight of single chip in aluminum pouch (no sticker) [appendix B] | Passed | Yes <input type="checkbox"/> No <input type="checkbox"/> |
| | Measurements of blister housing diameter and fluorescein colored capillary [appendix C] | | |
| | Pouches of chips are tightly sealed. | | |

Form: FQM-740-7

Rev.: 4.0

Rev. Date: 14.01.21

Page: 1 of 10

DiagnosTear, Ltd.

In Coming Inspection Form I - Visual and COA

| | |
|---|--------------------|
| Expiration Date If not declared, the expiry date will be one year from the date of receipt. | Expiry Date: _____ |
|---|--------------------|

1.2. **Acceptance criteria Results of category I:** All the answers should be "Yes" or "N/A".
According to the acceptance criteria, fill the table below.

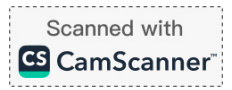
| | |
|--|--------------------|
| TearX chips, Lot: _____ is <input type="checkbox"/> Pass <input type="checkbox"/> Failed | Sample Size: _____ |
|--|--------------------|

2. Category II Test Results:

| Test | Yes/No | Form # | Testing Result | Comments |
|------------------------------------|--|-----------|--|----------|
| Efficacy Test is required: | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> | FQM-740-3 | Pass <input type="checkbox"/> Failed <input type="checkbox"/> | |
| Protein Measurement is required: | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> | SOP-4005 | Pass <input type="checkbox"/> Failed <input type="checkbox"/> | |
| Conjugate Measurement is required: | Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> | SOP-4021 | Pass <input type="checkbox"/> Failed <input type="checkbox"/> | |

3. Item Overall Approval and Status:

| | | |
|----------------------------|---|-----------------------------|
| Goods placed in quarantine | Yes <input type="checkbox"/> | Non Conformance No. _____ |
| | No <input type="checkbox"/> | Date: _____ Comments: _____ |
| Goods returned to supplier | Yes <input type="checkbox"/> No <input type="checkbox"/> | Date: _____ Comments: _____ |
| Goods released for stock | Yes <input type="checkbox"/> No <input type="checkbox"/> | Comments: _____ |



DiagnosTear, Ltd.

In Coming Inspection Form I – Visual and COA

4. Label:
The following label should be placed on the approved material:

| | | |
|---------------------|------------------------|-------------|
| Approved | LAB. 0001 REV. 1.0 | DiagnosTear |
| Description: _____ | | |
| Orig. Cat No: _____ | Orig. Lot No: _____ | |
| Diag. Cat No: _____ | Diag. Lot No: _____ | |
| PO No: _____ | Date: ___/___/___ | |
| Quantity: _____ | Exp. Date: ___/___/___ | |

5. Remarks: _____

6. Signature:

| | | |
|---------------------|------------------|-------------|
| Inspected By: _____ | Signature: _____ | Date: _____ |
|---------------------|------------------|-------------|

7. Approvals:

| | | | |
|--------------------|-----------------|------------------|-------------|
| Approved By: _____ | Position: _____ | Signature: _____ | Date: _____ |
|--------------------|-----------------|------------------|-------------|

| HISTORY LOG | | |
|-------------|---|----------------|
| REV. | CHANGES | EFFECTIVE DATE |
| 1.0 | NEW PROCEDURE | 16.10.2017 |
| 2.0 | UNKNOWN | |
| 3 | ADDING ANSI SAMPLING TABLE | 13-03-19 |
| 4 | ADDING RATIONAL FOR CATEGORIZED SAMPLING + DOCUMENTATION TABLES APENDIXES B+C | 14.01.2021 |

DiagnosTear, Ltd.

In Coming Inspection Form I – Visual and COA

Appendix A: Sampling Rational

Using ANSI Z 1.4 for risk-based Sample size selection:

| Shipment size | sample size code letter | | sample size | | AQL = 2.5% | |
|-----------------|-------------------------|-----------------------------|----------------------|-----------------------------|------------|-------|
| | Normal risk supplier | Critical risk item/supplier | Normal risk supplier | Critical risk item/supplier | Ac=0 | Re=1 |
| 2 to 8 | A | B | 2 | 3 | Ac=0 | Re=1 |
| 9 to 15 | B | C | 3 | 5 | Ac=0 | Re=1 |
| 16 to 25 | C | D | 5 | 8 | Ac=0 | Re=1 |
| 26 to 50 | D | E | 8 | 13 | Ac=0 | Re=1 |
| 51 to 90 | E | F | 13 | 20 | Ac=1 | Re=2 |
| 91 to 150 | F | G | 20 | 32 | Ac=1 | Re=2 |
| 151 to 280 | G | H | 32 | 50 | Ac=2 | Re=3 |
| 281 to 500 | H | J | 50 | 80 | Ac=2 | Re=3 |
| 501 to 1200 | J | K | 80 | 125 | Ac=5 | Re=6 |
| 1201 to 3200 | K | L | 125 | 200 | Ac=7 | Re=8 |
| 3201 to 10000 | L | M | 200 | 315 | Ac=10 | Re=11 |
| 10001 to 35000 | M | N | 315 | 500 | Ac=14 | Re=15 |
| 35001 to 150000 | N | P | 500 | 800 | Ac=14 | Re=15 |

The following table describes chip partition in the different measurement activity:

| Name of needed test | Sample size - required items (%) | Calculate No. of tests according to ANSI table | Rational for the sample size |
|--|----------------------------------|--|--|
| Integrity of pouched chips | 100 (n=80) | 100 (n=_____) | All items should be uncompromised The proportional representation of each of the incoming tests is correlated to the number of possible failure incidents mentioned in the risk analysis report |
| Items overall approval by using biochemistry testing per (FQM-740-8-PMT0041) TeaRx™ Validation test report form for LF, HSA and Lys standards as well as tear samples | 32.5 (n=26) | 32.5 (n=_____) | |
| Diameter of blister housing / Fluorescein inner coating of tear collecting capillary | 22.5 (n=18) | 22.5 (n=_____) | |
| Items weight | 22.5 (n=18) | 22.5 (n=_____) | |
| Items proper sealing in aluminum pouch | 22.5 (n=18) | 22.5 (n=_____) | |

DiagnosTear, Ltd.

In Coming Inspection Form I - Visual and COA

Appendix B: Weight Measurements of Chips

| # Chip | Weight gr | Results perending Acceptance Criteria |
|--------|-----------|---|
| 1 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 2 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 3 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 4 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 5 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 6 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 7 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 8 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 9 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 10 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 11 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 12 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 13 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 14 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 15 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 16 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 17 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 18 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 19 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 20 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 21 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 22 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 23 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 24 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 25 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 26 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 27 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 28 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

Form: FQM-740-7

Rev.: 4.0

Rev. Date: 14.01.21

Page: 5of: 10

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In Coming Inspection Form I – Visual and COA

| # Chip | Weight gr | Results according Acceptance Criteria |
|--------|-----------|---|
| 29 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 30 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 31 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 32 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 33 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 34 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 35 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 36 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 37 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 38 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 39 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 40 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 41 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 42 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 43 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 44 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 45 | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| Extra | | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

No. of Failures: _____

Acceptance criterion: Weight should be 10.90 gr \pm 0.15gr

Procedure:

1. Place weighing dish upside down on scale (AEL-039) aluminum foil from chip.
2. Place pouched chip on the weighing dish.
3. Measure weight and document in the above table

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Appendix C: Chip's physical measurements of blister housing AND Fluorescein dyeing of collecting capillary

| # Cap | Diameter of Blister housing mm | Capillary is dyed | Results according Acceptance Criteria |
|-------|--------------------------------|--|---|
| 1 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 2 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 3 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 4 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 5 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 6 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 7 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 8 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 9 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 10 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 11 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 12 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 13 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 14 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 15 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 16 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 17 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 18 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 19 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 20 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 21 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 22 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 23 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 24 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 25 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 26 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 27 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

In Coming Inspection Form I – Visual and COA

| # Chip | Diameter of blister housing mm | Capillary is dyed | Results according Acceptance Criteria |
|--------|--------------------------------|--|---|
| 28 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 29 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 30 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 31 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 32 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 33 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 34 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 35 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 36 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 37 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 38 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 39 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 40 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 41 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 42 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 43 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 44 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 45 | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| Extra | | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

No. of failures: _____

Acceptance criterion: Dimeter of blister housing should be 30.80 mm ± 0.15 AND capillary is dyed

Procedure:

1. Remove aluminum pouch from chip.
2. Measure diameter of blister housing as shown in the picture. Document in the above table
3. View tear collecting capillary and document if colored with dark orange

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In Coming Inspection Form I - Visual and COA

Appendix D: Sufficient sealing of aluminium pouch

| # Chip | Pouch is sealed | Results according Acceptance Criteria |
|--------|--|---|
| 1 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 2 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 3 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 4 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 5 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 6 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 7 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 8 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 9 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 10 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 11 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 12 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 13 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 14 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 15 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 16 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 17 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 18 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 19 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 20 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 21 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 22 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 23 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 24 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 25 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 26 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 27 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

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| # Chip | Pouch is sealed | Results according Acceptance Criteria |
|--------|--|---|
| 28 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 29 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 30 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 31 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 32 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 33 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 34 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 35 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 36 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 37 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 38 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 39 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 40 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 41 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 42 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 43 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 44 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| 45 | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |
| Extra | Yes <input type="checkbox"/> No <input type="checkbox"/> | Pass <input type="checkbox"/> Fail <input type="checkbox"/> |

No. of Failures: _____

Acceptance criterion: Pouch should be inflated in vacuum.

Procedure:

1. Assemble vacuum generating system- Sealed sphere + vacuum pump
2. Insert 3 pouched chips into the sphere.
3. Generate vacuum and document if all pouches keep inflating for 10 seconds.

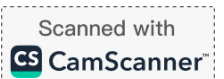


EXHIBIT E

CoC: P-16-0116-TearGuide-F0-005 Certificate of Conformity.docx

| | | |
|--------------------|-----|-----------------|
| Werk-Region | ... | ChipShop |
| Produktions-Region | ... | |
| Produktions-Linie | ... | |
| Produktions-Datum | ... | |

P-16-0116-TearGuide-F0-005-Certificate-of-Conformity

Aufgabe des Dokuments ist die Dokumentation des Freigabeprozesses und die Batch-Freigabe im Projekt-16-0116-TearGuide

Anderungshistorie

| Version | Änderungsgrund | Änderungsdatum | Änderer | Geprüft | Freigegeben | Freigegeben durch |
|---------|----------------|----------------|---------|---------|-------------|-------------------|
| 016 | Erstellung | 14.01.2016 | GR/... | 1.0 | 01.02.2016 | C-Gemad |
| 024 | Korrektur... | ... | FU... | 1.0 | 02.02.2016 | C-Gemad |

Referenzerte-/mitgelieferte Dokumente

| Dokument ID | Dokument Name | Version |
|-------------|---|---------|
| 16 | P-16-0116-TearGuide-F0-005-Produktionsanweisung | 1.0 |
| 24 | P-16-0116-TearGuide-F0-005-Produktionsanweisung | 1.0 |

Herangezogene GMP-Unterdokumente

| | |
|-----|-----|
| ... | ... |
| ... | ... |
| ... | ... |