Purchase Agreement
Contractnumber
Verplichtingennummer

PURCHASE AGREEMENT

BETWEEN

MEDIQ NEDERLAND B.V.
for and on behalf of
DE MINISTER VAN VOLKSGEZONDHEID WELZIJN EN SPORT

AND

MONDMASKERFABRIEK B.V.

FOR MEDICAL FACE MASKS type II/R

5.1.2e

Purchase Agreement
Contractnumber:
Verplichtingennummer:

SECTION I PURCHASE AGREEMENT

THIS CONTRACT IS MADE ON 18 May 2020 BETWEEN

1. **MEDIQ NEDERLAND B.V.**, a limited company organized and existing under the laws of the Netherlands, having its registered office at Rijnzathe 10, 3454 PV de Meern, the Netherlands for and on behalf of **DE STAAT DER NEDERLANDEN**, with its registered office in Den Haag, represented by the Minister van Volksgezondheid, Welzijn en Sport, hereinafter referred to as "**CUSTOMER**";

AND

2. **Mondmaskerfabriek B.V.**, a limited company organized and existing under the laws of the Netherlands, KvK nr: 77792149, having its registered office at H.J.E. Wenckebachweg 48, 1096AN, Amsterdam, the Netherlands, hereinafter referred to as "**CONTRACTOR**";

CUSTOMER and CONTRACTOR jointly referred to as the PARTIES and each separately as a PARTY.

RECITALS

A. CUSTOMER wishes to order the necessary goods in order to fight and contain the virus called COVID-19 for the benefit of, among others, hospitals, care homes and other care personnel in the Netherlands;
B. CONTRACTOR is willing to enter into an agreement with CUSTOMER to contribute to the fight and containment of the virus in the Netherlands;
C. Due to the unforeseen urgency and quick spread of the virus which is beyond the control of CUSTOMER, CUSTOMER is exempt from following the public procurement rules and invokes Article 2.32 (1, c) of the Dutch Public Procurement Act (Aanbestedingswet) 2012 to be able to directly enter into an agreement with CONTRACTOR in relation to the supply of certain goods;
D. CUSTOMER wishes to purchase medical face masks type II/R (*medische mondmaskers type II/R*). These medical face masks are medical devices Class I and CONTRACTOR has subsequently issued an offer;
E. Therefore, CUSTOMER and CONTRACTOR agree as follows.

Purchase Agreement
Contractnumber:
Verplichtingennummer:

THE PARTIES AGREE AS FOLLOWS

1 DEFINITIONS

Capitalised words and phrases use in this CONTRACT have the meanings:

"CONTRACT"	means this contract, its Schedules and Annexes, including but not limited to the General Purchase Conditions.
"CONTRACT PRICE"	means the price to be paid for the PRODUCTS as further set out in Section IV Pricing Schedule.
"OFFER"	means the offer issued by CONTRACTOR d.d. 30 April 2020.
"PRODUCT"	means medical face masks that comply with the required specifications and qualifications, including required CE certification, for medical face masks to be used in the healthcare sector by healthcare professionals as further detailed in Scope Schedule Section III.

2 SCOPE

CUSTOMER will purchase PRODUCTS through Purchase Orders.

This CONTRACT contains the following sections:

Section I:	Purchase Agreement;
Section II:	General Purchase Conditions;
Section III:	Scope Schedule;
Section IV:	Pricing Schedule.
Annex I:	Payment Schedule
Annex II:	Indicative Planning Table

Any ambiguity or contradiction will be resolved by reading the CONTRACT as a whole so that each provision will have effect. If a reading of the CONTRACT as a whole does not resolve the ambiguity or contradiction, then precedence will be given to Section I Purchase Agreement, and then to each section of the CONTRACT in the order it is listed.

3 DELIVERY

The PRODUCTS shall be delivered as detailed in the Purchase Order issued by CUSTOMER.

CUSTOMER shall purchase from CONTRACTOR on average 5.1.1c PRODUCTS **per week** produced by CONTRACTOR at full capacity for the duration of this CONTRACT and with a total of 5.1.1c 5.1.1c PRODUCTS. Until CONTRACTOR reaches full production capacity as provisionally specified in Annex 2, CUSTOMER shall obtain a number of PRODUCTS equal to 60% of the operational production capacity. 7

CUSTOMER has a right of first refusal of CONTRACTOR's remaining production capacity. By the expiration date of this agreement, CONTRACTOR shall have the right of first refusal in purchasing future production capacity, the volume of which is to be agreed between parties.

4 CONSIDERATION

In consideration of the obligations undertaken and fulfilled in accordance with the terms of this CONTRACT by CONTRACTOR under the CONTRACT, CUSTOMER agrees to pay the CONTRACT PRICE for the delivered PRODUCTS.

5 PURCHASE ORDERS

This CONTRACT provides for separate PURCHASE ORDERS for PRODUCTS.

6 EFFECTIVE DATE

The CONTRACT has an effective date of 18 May 2020 and will terminate on 18 May 2021.

7 NOTICES AND CONSULTATION

Notices under the CONTRACT must be made in writing and delivered to the following address specifications:

To CUSTOMER:	To CONTRACTOR:
MEDIQ NEDERLAND B.V.	Mondmaskerfabriek B.V.
Name 5.1.2e	Name: 5.1.2e
e-mail address: 5.1.2e @mediq.com	e-mail address: 5.1.2e @mondmaskerfabriek.nl
(mobile) phone number+31 5.1.2e	(mobile) phone number: + 5.1.2e

PARTIES will have structural and regular consultation (in principle on a weekly basis unless otherwise agreed) about the execution of the CONTRACT. The above-mentioned contact persons will be the focal points for such consultation. Topics that may be discussed are: (I) reporting on the status of the production and delivery of the PRODUCTS, (II) development of the virus and the state of emergency in The Netherlands, (III) expected demand and delivery within a foreseeable timeline.

During the consultations, definitive numbers of ordered PRODUCTS shall be determined.

8 GENERAL PROVISIONS

Purchase Agreement
Contractnumber:
Verplichtingennummer:

Amendments to this CONTRACT shall not be binding unless they are made in writing and signed by both PARTIES.

This CONTRACT contains the entire agreement of the PARTIES and supersedes and cancels any prior understandings and agreements of the PARTIES with respect to the subject matter hereof.

This CONTRACT may be executed in a number of identical separate counterparts, each of which for all purposes is deemed to be an original, but all of which shall collectively constitute one CONTRACT.

Signatories

For an 5.1.2e **alf of MEDIQ NEDERLAND B.V.**

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For and on behalf of
Mondmaskerfabriek B.V.

5.1.2e

For DE STAAT DER NEDERLANDEN,
DE MINISTER VAN VOLKSGEZONDHEID, WELZIJN EN SPORT,

5.1.2e

 5.1.2e

Purchase Agreement
Contractnumber:
Verplichtingennummer:

SECTION II THE GENERAL PURCHASE CONDITIONS

1. GENERAL APPLICABILITY

These General Purchase Conditions apply to (all requests for) offers, orders and agreements where a reference to these General Purchase Conditions is made, or the applicability is agreed in any other way, regarding the supply of goods to and the performance of services (hereinafter referred to as 'Deliveries' or 'PRODUCTS'). The supplier to be referred to as 'supplier' or 'CONTRACTOR').

2. ORDERS

a. Deliveries shall be made against purchase orders issued by CUSTOMER. Except in the event of Force Majeure, or if the supplier within one day after receipt of a purchase order rejects the purchase order, the supplier shall be obliged to accept purchase orders issued by CUSTOMER.
b. Acceptance of a purchase order issued by CUSTOMER implies acceptance of these General Purchase Conditions. No purchase order, acknowledgment form, or other ordering document or communication from the supplier shall vary the terms and conditions of these General Purchase Conditions.
c. If a purchase order carries an obvious spelling or calculation mistake or if an acknowledgment by the supplier of a purchase order issued by CUSTOMER deviates in any way from the order, CUSTOMER is only bound after it has explicitly declared in writing that it accepts the mistake or deviation. Acceptance by CUSTOMER of Deliveries, as well as payments for them made by CUSTOMER, does not imply any acceptance of any mistakes or acknowledgment of any deviations.

3. PRICE, INVOICING AND PAYMENT

a. The prices are only valid if mutually agreed and confirmed in writing by CUSTOMER and the agreed prices can only be changed after upfront mutual written agreement between CUSTOMER and the supplier. A price decrease is immediately effective, irrespective of the earlier date of the purchase order. In case of a delay in the delivery, the agreed price for the delivery date remains valid.
b. The agreed price is fixed in the currency of the country where the designated location of CUSTOMER for Deliveries is established and is excluding VAT. Invoices must be submitted to the designated location of CUSTOMER with reference numbers, be in conformity with the orders and itemised per position and include the position number(s). For as long as any part of these details is missing, CUSTOMER has the right to defer its obligation to pay the invoice in question.
c. CUSTOMER will pay after errorless invoicing within the agreed payment term. The agreed payment term is not a strict deadline. The supplier shall not withhold deliveries if CUSTOMER fails to make any payment when due.
d. Payment does not in any way imply the waiver of any right to come back on the performance of the Deliveries and/or invoices. Payment of the invoices of the supplier does not in any way imply the acceptance of any general conditions of the supplier that are mentioned or referred to on the invoices.
e. CUSTOMER is authorised to offset its debt, which is due and payable, against the debt owed by the supplier. Supplier is not authorised to offset any balances with any amounts owed by CUSTOMER.

4. INTELLECTUAL PROPERTY RIGHTS

a. If Deliveries or accompanying documentation are subject to intellectual property rights, CUSTOMER acquires a free right of its use via a non-exclusive, worldwide, perpetually renewable license. All intellectual property rights that arise as a result of the performance of the Deliveries by the supplier, its personnel or third parties that the supplier involves in the performance of the Deliveries, come to rest with CUSTOMER. On first demand of CUSTOMER, the supplier is obliged to do everything that is required to acquire and secure these rights.
b. The supplier guarantees that the Deliveries do not infringe the intellectual property rights of third parties. The supplier indemnifies and holds CUSTOMER harmless from and against any and all claims damages, liabilities, costs and expenses, including but not limited to court costs and reasonable attorneys' fees, asserted by any third party owing to (alleged) infringements in this regard.

5. PACKAGING AND SHIPMENT

The supplier will package the Deliveries to be supplied as economically, safely and carefully as possible and such that the shipment is easy to handle during transport and unloading and complies with all relevant laws and regulations. The supplier will ensure that the Deliveries reach their destination in good condition. Without prejudicing the aforementioned, the packaging

and the shipment must comply with all the applicable legislation and regulations including the Medical Device Regulation requirements (such as labelling and documentation requirements) and the agreed rules and procedures. CUSTOMER may reject Deliveries that do not comply with these requirements. Any return of any Deliveries, as well as any return of special packaging, irrespective of the reason, shall be for the cost of the supplier.

6. DELIVERY

a. All deliveries will be made to the agreed location according to the agreed delivery terms of the version of the Incoterms that applies at the moment that the order was placed.
b. The delivery date, dates or term(s) agreed apply as deadlines that must be strictly observed and apply to the whole delivery, including the accompanying documentation and labelling. Early delivery is not allowed unless agreed in writing in advance of delivery by CUSTOMER. Except in the event of Force Majeure, the supplier shall not be entitled to suspend or withhold delivery of the goods ordered by CUSTOMER. If circumstances occur that give cause to anticipate that the agreed delivery date, dates or term(s) will be exceeded, then the supplier must inform CUSTOMER of this immediately in writing. If the supplier exceeds any agreed delivery date, dates or term(s), CUSTOMER is entitled to an appropriate compensation by the supplier, without prejudice to CUSTOMER's other rights.
c. The supplier guarantees that the Deliveries are: - of good quality and defect free and in the case of performing services that they are performed by expert personnel using new materials; - entirely in accordance with the agreement or order, the specifications given and the reasonable expectations of CUSTOMER for as far as the characteristics, quality and reliability of the Deliveries are concerned; - suitable for the purpose for which the Deliveries are intended (i) in the nature of the case evident to the supplier or (ii) in accordance with the order; and - in compliance with all applicable legislation and regulations, including required technical documentation, including expiry date, instruction for use and labelling, any export license(s) required for the export of the Deliveries.
d. If any Deliveries are rejected, for whatever reason, CUSTOMER will inform the supplier about this and CUSTOMER can, at the option of CUSTOMER, require its replacement or repair, or terminate or cancel the order, without prejudice to CUSTOMER's other rights.

e. The supplier shall maintain adequate and accurate books and records with respect to the Deliveries for a period of at least the shelf life, respectively the life cycle of the Deliveries plus one (1) year, including but not limited to, manufacturing records and lot traceability records.
f. In addition, the supplier will be responsible for and shall ensure that all documentation required under the Medical Device Regulation ('MDR'), and any other applicable laws and/or regulations, will be available for inspection by the relevant authorities for a period at least equal to the minimum period required by applicable regulations and/or law.
g. The supplier shall:
- comply with all applicable rules and regulations relating to the nature, method of manufacture, packaging, instruction for use the language of the CUSTOMER entity purchasing the Deliveries, and labelling of the Deliveries as well as, at its own expense, obtain and maintain all necessary permits, licenses, manufacturing authorizations and registrations for the Deliveries;
- keep record from each production lot per Delivery, so that tracing of the Deliveries can be done according to the lot number ten (10) years after the production for all Deliveries, and will keep retention samples according MDR requirement;
- give notice to the Distributor without undue delay upon any changes of the Deliveries if the changes affect the agreed specifications and prior to such changes are implemented; and
- bear the direct costs (including recycling, if applicable) related to a field safety corrective action solely caused by the Deliveries and due to a request by an authorized authority.

7. TRANSFER OF OWNERSHIP AND RISK

The Deliveries are for the risk of the supplier until they have been delivered to the agreed destination and accepted in writing by an authorised CUSTOMER person stating his name. The ownership of the Deliveries passes to CUSTOMER at the latest at the moment of the aforementioned acceptance.

8. TRANSFER OF RIGHTS AND OBLIGATIONS

The supplier will not subcontract out the Deliveries or parts thereof to third parties and will not partially or wholly transfer the rights and obligations that it acquires by virtue of the agreement to third parties, without prior written permission from CUSTOMER. CUSTOMER may transfer any and all of its rights to third parties without having to obtain the approval of supplier.

9. CONFIDENTIALITY

The supplier shall not disclose to anyone or use, except with the prior written authorization of CUSTOMER any information that is considered confidential, if: (i) it concerns the Deliveries, (ii) it is delivered in written form marked "confidential", (iii) it is delivered orally, described as confidential and its confidential nature is confirmed in writing within thirty (30) days and (iv) in any event if the supplier might reasonably be expected to judge it as confidential, provided by CUSTOMER to the supplier or discerned by the supplier from information obtained from CUSTOMER in the course of performing its obligations, provided however, that such information shall not be considered as confidential if such information (i) is in the public domain or known by the supplier prior to disclosure, (ii) becomes known to the public after disclosure, other than through breach of this confidentiality obligation, (iii) becomes known to the supplier from a source other than CUSTOMER without breach of any obligation to preserve such information in confidence by such source, or (iv) is required by a court ruling or by law to be disclosed, provided such disclosure is subject to all available protection from further disclosure.

10. CORRUPT PRACTICES

The supplier shall maintain a high standard of moral and ethical behaviour concerning the Deliveries and shall conduct its business with the highest degree of integrity and in accordance with any law or regulation applicable to it or to its activities. In particular, the supplier undertakes that it has not offered, promised, given, authorized, solicited or accepted any undue pecuniary or other advantage of any kind in any way connected to the Deliveries and that it has taken reasonable measures to prevent its related third parties subject to its control or determining influence from doing so. The supplier will prohibit the practices of bribery, extortion or solicitation, trading in influence or laundering the proceeds of any of these corrupt practices, in relation to any public official, a political party or any person (in)directly related to the Deliveries.

11. GENERAL INDEMNITY

a. The supplier shall at all times defend, indemnify and hold CUSTOMER harmless from and against any and all damages, claims (including third party (product liability) claims and any claims and/or costs relating to suppliers' failure to comply with its obligations under the Medical Device Regulation), liabilities, costs and expenses, including but not limited to court costs and reasonable attorneys' fees, in connection with any third party claims arising out of the supply and use of the Deliveries or resulting directly or indirectly from any breach by the supplier of these General Conditions or an order or agreement and from any negligent act or omission of the supplier, except to the extent caused by (i) the gross negligence or intentional misconduct of CUSTOMER or (ii) a breach by CUSTOMER of any of the terms of these General Conditions.
b. Notwithstanding anything contained in these General Conditions to the contrary, CUSTOMER's total liability will, regardless of the nature of the claim or theory of recovery, not exceed the price of the Deliveries involved in the claim and in no event shall CUSTOMER be liable for any incidental, consequential, statutory, punitive or exemplary damages including without limitation, loss of property, personal injury, and loss of business or profits or other economic losses, regardless of the nature of the claim or theory of recovery.

12. APPLICABLE LAW AND COMPETENT COURT

Each of the Deliveries will be governed by the laws of the Netherlands. The applicability of the Vienna Sales Convention is excluded. All disputes between CUSTOMER and the supplier that may arise and for which no solution can be found in consultation with one another, shall exclusively be submitted to the court in The Hague, The Netherlands.

Purchase Agreement
Contractnumber:
Verplichtingennummer:

SECTION III SCOPE SCHEDULE

1. The medical face masks Type IIR (also referred to as 'surgical masks' type IIR) will have the appropriate CE-certification for a Class I medical device in accordance with Directive 93/42/EEC[1] and from 26 May 2021 with Regulation (EU) 2017/745[2].

2. The non-reusable medical device has the intended use of covering the mouth and nose providing a barrier to minimize the direct transmission of infective agents between staff and patient. Intended users are medical professionals. Intended environment is hospitals, nursing homes, general doctors' practise, dental practices and seminal medical environments.

3. The Masks will be tested in accordance with technical standard **EN 14683: 2019**. This standard specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

4. Subsequently, the CONTRACTOR will also apply for **ISO 13485: 2016**, which puts in place a Quality Management System for the production of medical devices according to Directive 93/ 42/ EEC.

5. CONTRACTOR will ensure that the medical face masks type IIR are certified in accordance with the requirements of EU-Directive 93/42/EEC. CONTRACTOR will notify the medical device at the relevant national competent authority in the Netherlands, by submitting the relevant product information and Declaration of Conformity.[3] CONTRACTOR will submit to CUSTOMER the formal notification of the Mask and will submit all relevant test-reports, certificates and other relevant documentation related to the certification of the Masks. CONTRACTOR will inform the CUSTOMER on the progress of the certification process on regular basis.
6. Delivery of the CE certified PRODUCT will commence as soon as possible after the advanced payment has been received by CONTRACTOR and will be done on a daily/weekly schedule as parties will agree upon separately.

[1] 93/42/EEC; OJ L 169 of 12 July 1993.
[2] Regulation (EU) 2017/745 of 5 April 2017.
[3] Notification in The Netherlands can be done in the Notis information system of CIBG/ Farmatec: https://www.farmatec.nl/medische-hulpmiddelen/benodigde-documenten-notificaties-en-aanvragen-exportverklaring.

5.1.2e

Purchase Agreement
Contractnumber:
Verplichtingennummer:

SECTION IV PRICING SCHEDULE

1. Pricing

1.1 The price for the PRODUCT is 5.1.1c which is a fixed price per PRODUCT for the duration of this CONTRACT (twelve months).

2. Payment

2.1 CUSTOMER will pay CONTRACTOR an advance payment of 5.1.1c 5.1.1c upon placement of the first order.

2.2 The advanced payment of 5.1.1c will be deducted in instalments of 5.1.1c from the prices of each subsequent Tranche of PRODUCTS delivered according to the schedule in Annex 1.

2.3 In case CONTRACTOR is unable to fulfil its contractual obligations under this Agreement, CONTRACTOR shall repay the advance payment of one million and two hundred thousand euro to CUSTOMER. This may include any financial or other assets of CONTRACTOR including proceeds derived from the market value of the equipment, machinery and raw materials up to the amount of the advance payment, at its sole discretion.

2.4 Payment for each Tranche if and when due will take place within **thirty (30)** after the full delivery of the Tranche in compliance with the Contractual specifications.

5.1.2e

Purchase Agreement
Contractnumber:
Verplichtingennummer:

ANNEX 1: Payment schedule

	Nr. PRODUCTS delivered	Price per PRODUCT	Amount due/ tranche	CONTRACTOR Repayment Instalment	CUSTOMER Amount due/ tranche
Advance payment					
Tranche 1					
Tranche 2					
Tranche 3					
Tranche 4					
Tranche 5					
Tranche 6					
Tranche 7					
Tranche 8					
Tranche 9					
Tranche 10				5.1.1c	
Tranche 11					
Tranche 12					
Tranche 13					
Tranche 14					
Tranche 15					
Tranche 16					
Tranche 17					
Tranche 18					
Total					

5.1.2e

Purchase Agreement
Contractnumber:
Verplichtingennummer:

ANNEX 2: Indicative planning table (milestones)

Topic	Week 18	Week 19	Week 20	Week 21	Week 22	Week 23	Week 24	Week 25
Machines	Installation and starting up of Machine 1 & 2	Test production. Machines 1&2	Ready for production Machine 1 & 2		Receiving Machine 3	Receiving Machine 4		Machine 3 & 4 ready for production
		Purchase order machine 3	Purchase order machine 4					
Certification	Formal confirmation of Certification and Quality plan. Acceptance of Testing procedure by supplier (XYZ)	Start certification process: a. CE marking, b. ISO 13485		Certification process: CE Marking ready (depending availability)				
Production				Start production	Production capacity of	Production capacity of	Production capacity of	Production capacity of

5.1.1c

5.1.2e