DECLARATION OF CONFORMITY

MEDICAL DEVICE REGULATION (EU) 2017/745

Legal Manufacturer

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

Authorized representative in the EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

This certificate is valid for the following product:

Non-sterile examination glove for single use
Classification: Class I according to MD Regulation (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Sizes	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Article codes	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

We hereby declare under sole responsibility that the CE marked product described above conforms to the requirements of the regulation for medical devices (EU) 2017/745.

Declaration based on Annex IV. Classification according to rule 5, Annex VIII. The conformity assessment is based on Annex II.

Applied standards: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Andreas Wöss
Director

Released by: Christian Rohrbach

This signed document is valid for all translations attached.

Issued : Singapore, 2022-01-10 **Expires:** 2024-01-09

KONFORMITÄTSERKLÄRUNG

MEDIZINPRODUKTEVERORDNUNG (EU) 2017/745

Hersteller

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

EU-Bevollmächtigter

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dieses Zertifikat ist gültig für die folgenden Produkte:

Nicht-steriler Untersuchungshandschuh für den Einmalgebrauch
Klassifizierung: Klasse I gemäß Medizinprodukteverordnung (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Größen	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnummern	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Wir bestätigen hiermit unter alleiniger Verantwortung, dass die CE gekennzeichneten Produkte mit den Anforderungen der Medizinprodukteverordnung (EU) 2017/745 übereinstimmen.

Erklärung basierend auf Anhang IV. Klassifizierung gemäß Regel 5, Anhang VIII. Konformitätsbewertung gemäß Anhang II.

Angewandte Normen: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Ausgestellt am: Singapore, 2022-01-10 **Gültig bis:** 2024-01-09

DÉCLARATION DE CONFORMITÉ

RÈGLEMENT POUR LES DISPOSITIFS MÉDICAUX (UE) 2017/745

Fabricant

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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Singapore 609434, Singapore
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SRN: SG-MF-000001645

Représentant UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Ce certificat est valable pour les produits suivants :

Gant d'examen non-stérile à usage unique
Classification : Classe I selon la règlement pour dispositifs médicaux (UE) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Tailles	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Numéros d'article	822790011	822790012	822790013	822790014	822790015	822790016	822790017	########

Par la présente, nous déclarons sous notre propre responsabilité que les produits portant le symbole CE sont conformes aux exigences de la règlement sur les dispositifs médicaux (EU) 2017/745.

La déclaration se fonde sur l'annexe IV. Classification selon la règle 5, annexe VIII. Évaluation de la conformité selon l'annexe II.

Normes appliquées : ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Délivré le : Singapore, 2022-01-10 **Valable jusqu'au :** 2024-01-09

DICHIARAZIONE DI CONFORMITÀ

REGOLAMENTO SUL DISPOSITIVO MEDICO (UE) 2017/745

Produttore

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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SRN: SG-MF-000001645

Rappresentante autorizzato nell'UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Questo certificato è valido per il seguente prodotto:

Guanto da esame monouso non sterile
Clasificazione: Classe I secondo il regolamento dispositivi medici (UE) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Misure	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Codici articolo	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE sopra descritto soddisfa i requisiti del regolamento sui dispositivi medici (UE) 2017/745 .

Dichiarazione basata sull'allegato IV. Classificazione secondo la regola 5, allegato VIII. La valutazione della conformità si basa sull'allegato II.

Norme applicate: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Rilasciato : Singapore, 2022-01-10 **Scade:** 2024-01-09

CONFORMITEITSVERKLARING

VERORDENING MEDISCHE PRODUCTEN (EU) 2017/745

Fabrikant

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Gemachtigde EU

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sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dit certificaat is geldig voor de volgende producten:

Niet-steriele onderzoekshandschoenen voor eenmalig gebruik
Classificatie: Klasse I volgens Verordening (EU) 2017/745 betreffende medische hulpmiddelen

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Maten	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnummers	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Wij verklaren hierbij onder uitsluitende verantwoordelijkheid, dat de CE-gemarkeerde producten voldoen aan de vereisten van de Verordening Medische Hulpmiddelen (EU) 2017/745.

Verklaring op basis van bijlage IV. Classificatie volgens regel 5, bijlage VIII. De conformiteitsbeoordeling is gebaseerd op bijlage II.

Toegepaste normen: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Uitgegeven op: Singapore, 2022-01-10 **Geldig tot:** 2024-01-09

DECLARACIÓN DE CONFORMIDAD

REGLAMENTO (UE) 2017/745 DE PRODUCTOS MEDICINALES

Fabricante

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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sempermed@semperitgroup.com
SRN: SG-MF-000001645

Representante de la UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

El presente certificado es válido para los siguientes productos:

Guante de exploración no estéril para un solo uso
Clasificación: Clase I según el Reglamento de Productos Medicinales (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Tamaños	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Número de artículo	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Por la presente confirmamos bajo nuestra exclusiva responsabilidad que los productos con marcado CE cumplen con los requisitos del Reglamento (UE) 2017/745 sobre productos sanitarios.

Declaración basada en el anexo IV. Clasificación según la norma 5 del anexo VIII. La evaluación de la conformidad se basa en el anexo II.

Normas aplicadas: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Expedido el: Singapore, 2022-01-10 **Válido hasta:** 2024-01-09

DECLARAÇÃO DE CONFORMIDADE

REGULAMENTO (UE) 2017/745 SOBRE DISPOSITIVOS MÉDICOS

Fabricante

Semperit Investments Asia Pte. Ltd.
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sempermed@semperitgroup.com
SRN: SG-MF-000001645

Representante da UE

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Este certificado é válido para os seguintes produtos:

Luva de exame não estéril para uso único
Classificação: Classe I de acordo com o regulamento de Dispositivos Médicos (UE) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Tamanhos	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Números de artigo	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Declaramos desta forma, sob a nossa exclusiva responsabilidade, que os produtos com a marca CE estão em conformidade com os requisitos da Regulamento de Dispositivos Médicos (UE) 2017/745 .

Declaração baseada no Anexo IV. Classificação de acordo com a regra 5, Anexo VIII. Avaliação da conformidade com base no Anexo II.

Normas aplicadas: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Emitido em: Singapore, 2022-01-10 **Válido até:** 2024-01-09

DEKLARATON OM ÖVERENSSTÄMMELSE

FÖRORDNING (EU) 2017/745 MEDICINTEKNISKA PRODUKTER

Tillverkare

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

Behörig representant hos EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Detta certifikat gäller följande produkt:

Icke-steril inspektionshandske för engångsanvändning
Klassificering: Klass I enligt EU-förordning för medicintek-niska produkter (MD) (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Storlekar	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelkoder	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Vi förklarar härmed under eget exklusivt ansvar att ovan beskrivna, CE-markerade produkt stämmer överens med erforderliga i förordning för medicinska produkter (EU) 2017/745.

Förklaring på grundval av bilaga IV. Klassificering enligt regel 5, bilaga VIII. Bedömningen av överensstämmelse grundar sig på bilaga II.

Tillämpade standarder: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Daterad : Singapore, 2022-01-10 **Giltig till:** 2024-01-09

KONFORMITETSERKLÆRING

FORORDNING (EU) 2017/745 OM MEDICINSK UDSTYR

Producent

Semperit Investments Asia Pte. Ltd.
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sempermed@semperitgroup.com
SRN: SG-MF-000001645

EU-befuldmægtigede

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sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dette certifikat er gyldigt for følgende produkter:

Ikke-steril undersøgelseshandske til engangsbrug
Klassificering: Klasse I jævnfør (EU) 2017/745 -forordningen for medicinsk udstyr

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Størrelser	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikelnumre	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Vi bekræfter hermed under fuldt ansvar, at de ovenfor nævnte CE-mærkede produkter stemmer overens med de krav i forordningen for medicinsk udstyr (EU) 2017/745.

Erklæring på grundlag af bilag IV. Klassificering i henhold til regel 5, bilag VIII. Overensstemmelsesvurderingen er baseret på bilag II.

Anvendte standarder: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Udstedt den: Singapore, 2022-01-10 **Gyldig til:** 2024-01-09

KONFORMITETSERKLÆRING

FORORDNING FOR MEDISINSK UTSTYR (EU) 2017/745

Produsent

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
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SRN: SG-MF-000001645

Autorisert representant i EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Dette sertifikatet er gyldig for følgende produkter:

Ikke-steril undersøkelseshanske for engangsbruk
Klassifisering: Klasse I i henhold til forordning for medisinsk utstyr (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Størrelser	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikkelnumre	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Vi erklærer herved under eneansvar at det CE-merkede produktet oppfyller de kravene i Uredbet for medisinsk utstyr (EU) 2017/745.

Erklæring basert på vedlegg IV. Klassifisering i henhold til regel nr. 5, vedlegg VIII. Samsvarsvurderingen er basert på vedlegg II.

Relevante standarder: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Utstedt den: Singapore, 2022-01-10 **Gyldig til:** 2024-01-09

VAATIMUSTENMUKAISUUSVAKUUTUS

LÄÄKINNÄLLISIÄ LAITTEITA KOSKEVA ASETUS (EU) 2017/745

Valmistaja

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
#29-03 to 06 The JTC Summit,
Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

EU:n valtuutettu edustaja

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Tämä sertifikaatti koskee seuraavia tuotteita:

Kertakäyttöinen ei-steriili tutkimuskäsine
Luokitus: Luokka I lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukaisesti

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Koot	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Tuotenumerot	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Täten vahvistamme yksinomaisella vastuullamme, että CE-merkityt tuotteet vastaavat lääkinnällisiä laitteita koskevan asetuksen (EU) 2017/745 mukaisia vaatimuksia.

Liitteeseen IV perustuva julistus. Luokitus liitteen VIII 5 säännön mukaisesti. Vaatimustenmukaisuuden arviointi perustuu liitteeseen II.

Sovelletut standardit: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Laadittu : Singapore, 2022-01-10 **Voimassa (asti):** 2024-01-09

ATITIKTIES DEKLARACIJA

REGLAMENTAS DĖL MEDICINOS PRIETAISŲ (ES) 2017/745

Gamintojas

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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SRN: SG-MF-000001645

ES įgaliotas asmuo

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
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SRN: AT-AR-000000735

Šis sertifikatas galioja toliau nurodytiems produktams:

Nesterilios vienkartinio naudojimo apžiūros pirštinės
Klasifikacija: I klasė pagal reglamentą dėl medicinos prietaisų (ES) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Dydžiai	5,5	6	6,5	7	7,5	8	8,5	9
Prekių numeriai	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Prisiimdami visą atsakomybę šiuo dokumentu patvirtiname, kad CE paženklinti produktai atitinka reglamentą dėl medicinos prietaisų (ES) 2017/745 reikalavimus.

Deklaracija, pagrįsta IV priedu. Klasifikavimas pagal VIII priedo 5 taisyklę. Atitikties įvertinimas pagal II priedą.

Taikomi standartai: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Išduota : Singapore, 2022-01-10 **Galioja iki:** 2024-01-09

ATBILSTĪBAS DEKLARĀCIJA

MEDICĪNAS IERĪČU REGULA (ES) 2017/745

Likumīgais ražotājs

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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Singapore 609434, Singapore
sempermed@semperitgroup.com
SRN: SG-MF-000001645

Pilnvarotais pārstāvis ES

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Šis sertifikāts ir derīgs šādam produktam:

Nesterili izmeklēšanas cimdi vienreizējai lietošanai
Klasifikācija: I klase saskaņā ar medicīnas ierīču Regulu (ES) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Izmēri	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Artikula numurs	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Ar šo mēs apliecinām, ka iepriekš aprakstītais produkts ar CE marķējumu atbilst medicīnas ierīču (ES) 2017/745 regulas prasībām.

Deklarācija, pamatojoties uz IV pielikumu. Klasifikācija saskaņā ar VIII pielikuma 5. noteikumu. Atbilstības novērtēšanas pamatā ir II pielikums.

Piemērotie standarti: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Izdots : Singapore, 2022-01-10 **Derīgs līdz:** 2024-01-09

VASTAVUSDEKLARATSIOON

MEDITSIINITOODETE MÄÄRUS (EL) 2017/745

Tootja

Semperit Investments Asia Pte. Ltd.
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Volitatud esindaja EL-is

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SRN: AT-AR-000000735

See sertifikaat kehtib järgmistele toodetele:

Mittesteriilne läbivaatuskinnas ühekordseks kasutuseks
Klassifikatsioon: I klass kooskõlas meditsiinitoodete määrusega (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Suurused	5,5	6	6,5	7	7,5	8	8,5	9
Tootenumbrid	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Kinnitame oma ainuvastutusel, et CE-märgisega tooted on kooskõlas meditsiinitoodete määruse (EU) 2017/745 nõuetega.

Deklaratsioon põhineb IV lisal. Klassifikatsioon kooskõlas VIII lisa 5. reegliga. Vastavushindamine põhineb II lisal.

Kohaldatud normid: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Välja andmise aeg : Singapore, 2022-01-10 **Kehtivusaeg:** 2024-01-09

PROHLÁŠENÍ O SHODĚ

NAŘÍZENÍ O ZDRAVOTNICKÝCH PROSTŘEDCÍCH (EU) 2017/745

Výrobce

Semperit Investments Asia Pte. Ltd.
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EU zplnomocněný zástupce

Semperit Technische Produkte Gesellschaft m.b.H.
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sempermed@semperitgroup.com
SRN: AT-AR-000000735

Tento certifikát je platný pro následující produkty:

Nesterilní vyšetřovací rukavice pro jednorázové použití
Klasifikace Třída I podle nařízení o zdravotnických prostředcích (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Velikosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Číslo produktu	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Tímto potvrzujeme s výlučnou odpovědností, že produkty označené CE souhlasí se požadavky nařízení o zdravotnických prostředcích (EU) 2017/745.

Prohlášení na základě přílohy IV. Klasifikace podle pravidla 5 přílohy VIII. Posouzení shody je založeno na příloze II.

Použité normy: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Vystaveno dne: Singapore, 2022-01-10 **Platné do:** 2024-01-09

VYHLÁSENIE O ZHODE

NARIADENIE (EU) 2017/745 O ZDRAVOTNÍCKYCH POMÔCKACH

Výrobca

Semperit Investments Asia Pte. Ltd.
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Splnomocnenec pre EÚ

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sempermed@semperitgroup.com
SRN: AT-AR-000000735

Tento certifikát je platný pre nasledujúce body:

Nesterilné vyšetrovacie rukavice na jedno použitie
Klasifikácia: Trieda I podľa Nariadenia (EU) 2017/745 o zdravotníckych pomôckach

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Veľkosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Výrobné čísla	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Týmto vo svojej výhradnej zodpovednosti potvrdzujeme, že výrobky označené symbolom CE sú v súlade so požiadavkami Nariadenia (EU) 2017/745 o zdravotníckych pomôckach.

Vyhlásenie na základe prílohy IV. Klasifikácia podľa pravidla 5 prílohy VIII. Posudzovanie zhody je založené na prílohe II.

Súvisiace normy: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Vyhotovené dňa: Singapore, 2022-01-10 **Platné do:** 2024-01-09

MEGFELELŐSÉGI NYILATKOZAT

ORVOSTECHNIKAI ESZKÖZÖKRŐL SZÓLÓ (EU) 2017/745 RENDELET

Gyártó

Semperit Investments Asia Pte. Ltd.
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EU-meghatalmazott

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Triester Bundesstraße 26, 2632 Wimpassing, Austria
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SRN: AT-AR-000000735

Ez a tanúsítvány a következő termékekre érvényes:

Egyszer használatos, nem steril vizsgálati kesztyű
Osztályozás: I. osztály az orvostechnikai eszközökről szóló (EU) 2017/745 rendelet szerint

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Méretek	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Cikkszámok	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Ezennel kizárólagos felelősségünk mellett kijelentjük, hogy a CE jelzésű termékek eszközökről szóló (EU) 2017/745 rendelet alapvető előírásainak.

Con la presente, dichiariamo sotto la nostra esclusiva responsabilità che il prodotto con marchio CE sopra descritto soddisfa i requisiti del regolamento sui dispositivi medici (UE) 2017/745 .

Alkalmazott szabványok: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Kelt : Singapore, 2022-01-10 **Érvényes:** 2024-01-09

IZJAVA O SKLADNOSTI

UREDBA O MEDICINSKIH PRIPOMOČKIH (EU) 2017/745/EGS

Proizvajalec

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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SRN: SG-MF-000001645

Pooblaščen zastopnik EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
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SRN: AT-AR-000000735

To potrdilo velja za naslednje izdelke:

Nesterilne rokavice za preglede za enkratno uporabo
Klasifikacija: Razred I v skladu z Uredbo o medicinskih pripomočkih (EU) 2017/745/EGS

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Velikosti	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Številke izdelkov	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

S to izključno odgovornostjo izjavljamo, da so izdelki z oznako CE v skladu z zahtevami Uredbe za medicinske pripomočke (EU) 2017/745.

Izjava na podlagi Priloge IV. Razvrstitev v skladu s Prilogo VIII k Pravilniku 5. Ocenjevanje skladnosti temelji na Prilogi II.

Uporabljeni standardi: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Izdano dne: Singapore, 2022-01-10 **Veljavno do:** 2024-01-09

IZJAVA O SUKLADNOSTI

UREDBA O MEDICINSKIM PROIZVODIMA (EU) 2017/745

Proizvođač

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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sempermed@semperitgroup.com
SRN: SG-MF-000001645

Ovlašteni predstavnik u EU

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Ovaj certifikat vrijedi za sljedeće proizvode:

Nesterilne rukavice za pregled za jednokratnu uporabu
Klasifikacija: Klasa I. prema Direktivi o medicinskim proizvodima (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Veličine	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Br. artikla	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Ovim putem izjavljujemo pod punom odgovornošću da su proizvodi s CE oznakom sukladni s zahtjevima Uredbe o medicinskim proizvodima (EU) 2017/745.

Izjava se temelji na Prilogu IV. Klasifikacija prema pravilu 5, Prilog VIII. Ocjenjivanje sukladnosti prema Prilogu II.

Primijenjene norme: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Izdano dana: Singapore, 2022-01-10 **Vrijedi do:** 2024-01-09

DEKLARACJA ZGODNOŚCI

ROZPORZĄDZENIE W SPRAWIE WYROBÓW MEDYCZNYCH (UE) 2017/745

Producent

Semperit Investments Asia Pte. Ltd.
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SRN: SG-MF-000001645

Autoryzowany przedstawiciel w UE

Semperit Technische Produkte Gesellschaft m.b.H.
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SRN: AT-AR-000000735

Niniejszy certyfikat obowiązuje w odniesieniu do następującego produktu:

Niesterylne rękawice medyczne jednorazowego użytku
Klasyfikacja: Klasa I zgodnie z rozporządzeniem (UE) 2017/745 w sprawie wyrobów medycznych

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Rozmiary	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Numery artykułów	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Niniejszym oświadczamy, na naszą wyłączną odpowiedzialność, że opisany powyżej produkt z oznakowaniem CE jest zgodny z wymogami rozporządzenia w sprawie wyrobów medycznych (UE) 2017/745.

Deklaracja na podstawie załącznika IV. Klasyfikacja jest zgodna z zasadą 5, załącznik VIII. Ocenę zgodności przeprowadza się na podstawie załącznika II.

Zastosowane normy: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Data wydania: Singapore, 2022-01-10 **Data ważności:** 2024-01-09

DECLARAȚIE DE CONFORMITATE

REGULAMENTULUI PRIVIND PRODUSELE MEDICALE (EU) 2017/745

Producător

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Persoană împuternicită EU

Semperit Technische Produkte Gesellschaft m.b.H.
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SRN: AT-AR-000000735

Acest certificat este valabil pentru următoarele produse:

Mânușă de consult nesterilă de unică folosință
clasificare: Clasa I conform règlementi privind produsele medicale (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

mărimi	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Numerele de articole	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Prin prezenta confirmăm preluând toată responsabilitatea că produsele marcate CE corespund cerințelor din Regulamentului privind produsele medicale (EU) 2017/745 .

Declarație bazată pe anexa IV. Clasificare în conformitate cu regula 5, anexa VIII. Evaluarea conformității se bazează pe anexa II.

Normele aplicate: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Eliberat la data de: Singapore, 2022-01-10 **Valabil până în:** 2024-01-09

ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ

ΚΑΝΟΝΙΣΜΟΣ (ΕΕ) 2017/745 ΠΕΡΙ ΙΑΤΡΟΤΕΧΝΟΛΟΓΙΚΩΝ ΠΡΟΪΟΝΤΩΝ

Κατασκευαστής

Semperit Investments Asia Pte. Ltd.
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#29-03 to 06 The JTC Summit,
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SRN: SG-MF-000001645

Εξουσιοδοτημένος αντιπρόσωπος στην ΕΕ

Semperit Technische Produkte Gesellschaft m.b.H.
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SRN: AT-AR-000000735

Το παρόν πιστοποιητικό ισχύει για τα ακόλουθα προϊόντα:

Μη αποστειρωμένο γάντι εξέτασης μιας χρήσης
Ταξινόμηση: Κατηγορία I σύμφωνα με την Κανονισμό (EU) 2017/745 περί ιατροτεχνολογικών προϊόντων

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Μεγέθη	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Αριθμοί προϊόντος	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Δια του παρόντος βεβαιώνουμε υπεύθυνα ότι τα προϊόντα με σήμανση CE ικανοποιούν τις απαιτήσεις της Κανονισμός (EU) 2017/745 περί ιατροτεχνολογικών προϊόντων.

Δήλωση με βάση το παράρτημα IV. Ταξινόμηση σύμφωνα με τον κανόνα 5, παράρτημα VIII. Η αξιολόγηση της συμμόρφωσης βασίζεται στο παράρτημα II.

Εφαρμοζόμενα πρότυπα: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

Εκδόθηκε : Singapore, 2022-01-10 **Ισχύει έως:** 2024-01-09

ДЕКЛАРАЦИЯ ЗА СЪВМЕСТИМОСТ НА

РЕГЛАМЕНТ ЗА МЕДИЦИНСКИТЕ ПРОДУКТИ (EU) 2017/745

Производител

Semperit Investments Asia Pte. Ltd.
8 Jurong Town Hall Road,
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SRN: SG-MF-000001645

Упълномощен представител в ЕС

Semperit Technische Produkte Gesellschaft m.b.H.
Triester Bundesstraße 26, 2632 Wimpassing, Austria
sempermed@semperitgroup.com
SRN: AT-AR-000000735

Настоящият сертификат важи за следните продукти:

Нестерилна ръкавица за преглед за еднократна употреба
Класификация: Клас I съгл. Регламент за медицинските продукти (EU) 2017/745

Basic UDI-DI: 9001570LFM-097NA-N-5YN

sempermed derma PF innerpaper

Размери	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Номера на артикулите	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

С настоящето потвърждаваме при самостоятелна отговорност, че продуктите с маркировка CE съответстват на изисквания от Регламент за медицинските продукти (EU) 2017/745.

Декларация въз основа на приложение IV. Класификация съгласно правило 5, приложение VIII. Оценката на съответствието се основава на приложение II.

Приложими норми: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

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UYGUNLUK BEYANI

TIBBİ CİHAZLAR HAKKINDA 2017/745 TÜZÜĞÜ (AB)

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Bu sertifika aşağıdaki ürün için geçerlidir:

Tek kullanımlık steril olmayan muayene eldiveni
Sınıflandırma: Tıbbi cihazlarla ilgili 2017/745 (AB) sayılı Tüzük uyarınca Sınıf I

Basic UDI-DI: 9001570LFM-097NA-N-5YN

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Boyutlar	**5,5**	**6**	**6,5**	**7**	**7,5**	**8**	**8,5**	**9**
Ürün numaraları	822790011	822790012	822790013	822790014	822790015	822790016	822790017	822790018

Yukarıda açıklanan CE işaretli ürünün (AB) 2017/745 sayılı tıbbi cihazlara ilişkin Yönetmeliği koşullarına uygun olduğunu tek sorumluluğumuzda beyan ederiz.

Ek IV'e dayalı beyan. Kural 5, Ek VIII'e göre sınıflandırma. Uygunluk değerlendirmesi Ek II'a dayanmaktadır.

Uygulamalı standartlar: ASTM D3578-19, ASTM D6319-19 or ASTM D5250-19, ASTM F1671/F1671M-13, EN ISO 20417:2021, EN 455-1:2020, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, EN 62366-1:2015 + AC:2016 + A1:2020, EN ISO 10993-1:2020, EN ISO 13485:2016 + AC:2018 + A11:2021, EN ISO 14971:2019 + A11:2021, EN ISO 15223-1:2021, ISO 10282:2014, ISO 2230:2002, MEDDEV 2.7/1 revision 4, Regulation (EC) 1907/2006

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