

**DOC. TITLE:** RE00184748 Declaration of Conformity MDR Genius 3 Tympanic Thermometer and Base

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1

## DECLARATION OF CONFORMITY



**CardinalHealth**

**MDR:** We, Cardinal Health 200 LLC, declare that the products covered in this EU Declaration of Conformity meet the provision of the Medical Device Regulation (EU) 2017/745.


<b>Declaration of Conformity Number</b>	RE00184748
<b>Technical Documentation Number</b>	RE00135119
<b>Manufacturer's Name</b>	Cardinal Health 200, LLC
<b>Manufacturer's Address</b>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Single Registration Number</b>	US-MF-000006765
<b>Authorized Representative's Name and Address</b>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Notified body's Name and Identification Number</b>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>CE Certificate Number</b>	G10 056759 0040 Rev.00
<b>Product Category</b>	Non-Contact Digital Thermometers
<b>Basic UDI-DI</b>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Product Code, Trade Name and Description</b>	303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Intended Purpose</b>	The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Classification and Rule</b>	Class: IIa Rule: 10
<b>Common Specifications</b>	Not Applicable
<b>Where appropriate, add applicable Union legislation</b>	RoHS 2015/863 REACH 1907/2006
<b>Conformity Assessment</b>	Annex IX Chapters I and III

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<b>SIGNATURE SECTION</b>	
<b>This EU Declaration of Conformity is issued for and on behalf of and under the sole responsibility of the Legal Manufacturer identified above.</b>	
<b>Place of Issue</b>	<b>Waukegan, IL 60085 USA</b>
<b>Signature/ Date</b>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Name and Function</b>	Soumitra Shilotri Regulatory Affairs

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**CZECH**

<b>PROHLÁŠENÍ O SHODĚ</b> <b>DECLARATION OF CONFORMITY</b>	
 <b>CardinalHealth</b>	<b>MDR:</b> Naše společnost, Cardinal Health 200 LLC, prohlašuje, že výrobky uvedené v tomto EU prohlášení o shodě splňují ustanovení nařízení (EU) 2017/745 o zdravotnických prostředcích.
<b>Číslo prohlášení o shodě</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Číslo technické dokumentace</b> <i>Technical Documentation Number</i>	RE00135119
<b>Název výrobce</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa výrobce</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Jediné registrační číslo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Název a adresa autorizovaného zástupce</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Název a identifikační číslo oznámeného subjektu</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Číslo certifikátu CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Kategorie výrobku</b> <i>Product Category</i>	Bezkontaktní digitální teploměry Non-Contact Digital Thermometers
<b>Základní UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Kód, obchodní název a popis výrobku</b> <i>Product Code, Trade Name and Description</i>	303013 – Tympanický teploměr Genius™ 3 a základna 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Účel použití</b> <i>Intended Purpose</i>	Tympanický teploměr Genius™ 3 a základna jsou určeny k měření teploty z tympanické membrány. The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Klasifikace a pravidlo</b> <i>Classification and Rule</i>	Třída/ Class: IIa Pravidlo/ Rule: 10
<b>Obecná specifikace</b>	Nelze uplatnit (N/A)


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<b>PROHLÁŠENÍ O SHODĚ</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Common Specifications</i>	
<b>Dle potřeby doplňte příslušný předpis Unie</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Posouzení shody</b> <i>Conformity Assessment</i>	Příloha IX, kapitoly I a III/ Annex IX Chapters I and III

<b>PODPISOVÁ ČÁST</b> <i>SIGNATURE SECTION</i>	
<b>Toto EU prohlášení o shodě se vydává jménem a na výhradní odpovědnost oprávněného výrobce uvedeného výše.</b>	
<b>Místo vydání</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Podpis / Datum</b> <i>Signature/ Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Jméno a funkce</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Oddělení regulačních záležitostí

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**DANISH**

<b>PROHLÁŠENÍ O SHODĚ</b> <i>DECLARATION OF CONFORMITY</i>	
 <b>CardinalHealth</b>	<b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer, at produkterne dækket af denne EU-overensstemmelseserklæring overholder kravene i Forordning (EU) 2017/745 om medicinsk udstyr.
<b>Overensstemmelseserklæringsnummer</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Teknisk dokumentationsnummer</b> <i>Technical Documentation Number</i>	RE00135119
<b>Producentens navn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Producentens adresse</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkelt registreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Navn og adresse på godkendt repræsentant</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Navn og identifikationsnummer på bemyndiget organ</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>CE-certifikationsnummer</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Produktkategori</b> <i>Product Category</i>	Digitale termometre uden kontakt Non-Contact Digital Thermometers
<b>Grundlæggende UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Produktkode(r), handelsnavn og beskrivelse</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 Tympanisk termometer og base 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Tiltænkt formål</b> <i>Intended Purpose</i>	Genius™ 3 Tympanisk termometer og base er beregnet til at give temperaturmålinger fra trommehinden.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.


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<b>PROHLÁŠENÍ O SHODĚ</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Klassificering og regel</b> <i>Classification and Rule</i>	Klasse /Class: IIa Regel/ Rule: 10
<b>Fælles specifikationer</b> <i>Common Specifications</i>	Ikke relevant (N/A)
<b>Hvor relevant, tilføj gældende union-lovgivning</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Overensstemmelsesvurdering</b> <i>Conformity Assessment</i>	Bilag IX, kapitel I og III/ Annex IX Chapters I and III

<b>SIGNATURAFSNIT</b> <i>SIGNATURE SECTION</i>	
Denne EU-overensstemmelseserklæring er udstedt for og på vegne af og under eneansvar for den juridiske producent, der er identificeret ovenfor.	
<b>Udstedelsessted</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Underskrift / Dato</b> <i>Signature/ Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Navn og funktion</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Lovgivningsanliggender

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**DUTCH**

<b>CONFORMITEITSVERKLARING DECLARATION OF CONFORMITY</b>	
 <b>CardinalHealth</b>	<p><b>MDR:</b> Wij, Cardinal Health 200 LLC, verklaren dat de producten die onder deze EU-conformiteitsverklaring vallen, voldoen aan Verordening (EU) 2017/745 betreffende medische hulpmiddelen.</p>
<b>Nummer conformiteitsverklaring</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Nummer technische documentatie</b> <i>Technical Documentation Number</i>	RE00135119
<b>Naam fabrikant</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adres van de fabrikant</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkel registratienummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Naam en adres van de erkende vertegenwoordiger</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Naam en identificatienummer van de aangemelde instantie</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Nummer CE-markering</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Productcategorie</b> <i>Product Category</i>	Contactloze digitale thermometers Non-Contact Digital Thermometers
<b>Basis UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Productcode, handelsnaam en beschrijving</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 oorthermometer en houder 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Beoogd doel</b> <i>Intended Purpose</i>	De genius™ 3 oorthermometer en houder is bedoeld om de temperatuur bij het trommelvlies te meten.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Classificatie en regel</b>	Klasse /Class: IIa


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<b>CONFORMITEITSVERKLARING</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Classification and Rule</i>	Regel/ Rule: 10
<b>Algemene specificities</b> <i>Common Specifications</i>	Niet van toepassing (N/A)
<b>Voeg, indien van toepassing, de toepasselijke wetgeving van de Unie toe</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Conformiteitsbeoordeling</b> <i>Conformity Assessment</i>	Bijlage IX Hoofdstuk I en III/ Annex IX Chapters I and III

<b>HANDTEKENINGGEDEELTE</b> <i>SIGNATURE SECTION</i>	
<b>Deze EU-conformiteitsverklaring wordt voor en namens en uitsluitend onder de verantwoordelijkheid van de fabrikant afgegeven.</b>	
<b>Plaats van afgifte</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Handtekening/Datum</b> <i>Signature/ Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Naam en functie</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Regelgevingszaken

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**FINNISH**

<b>VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY</b>	
 <b>CardinalHealth</b>	<b>MDR:</b> Me, Cardinal Health 200 LLC, vakuutamme, että tässä EU-vaatimustenmukaisuusvakuutuksessa kuvatut tuotteet täyttävät lääkintälaitteasetuksen (EU) 2017/745 vaatimukset.
<b>VAATIMUSTENMUKAISUUSVAKUUTUS</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Teknisen dokumentin numero</b> <i>Technical Documentation Number</i>	RE00135119
<b>Valmistajan nimi</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Valmistajan osoite</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Yksittäinen rekisterinumero</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Valtuutetun edustajan nimi ja osoite</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Ilmoitetun laitoksen nimi ja tunnusnumero</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>CE-sertifikaatin numero</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Tuotekategoria</b> <i>Product Category</i>	Kontaktittomat digitaaliset lämpömittarit Non-Contact Digital Thermometers
<b>Yksilöllinen laitemallin tunniste (Basic UDI-DI)</b> <i>Basic UDI-DI</i>	0630140000000000000000001566L
<b>EMDN</b>	V0301010202
<b>Tuotekoodi, kaupan nimi ja kuvaus</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 -korvalämpömittari ja alusta 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Käyttötarkoitus</b> <i>Intended Purpose</i>	Genius™ 3 -korvalämpömittari ja alusta on tarkoitettu lämpötilan mittaamiseen tärykalvosta.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Luokittelu ja sääntö</b>	Luokka/ Classification: IIA


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<b>VAATIMUSTENMUKAISUUSVAKUUTUS DECLARATION OF CONFORMITY</b>	
<i>Classification and Rule</i>	Sääntö/ Rule: 10
<b>Yleiset tekniset tiedot</b> <i>Common Specifications</i>	Ei sovellu (N/A)
<b>Lisää tarvittaessa soveltuva unionin lainsäädäntö</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Vaatimustenmukaisuuden arviointi</b> <i>Conformity Assessment</i>	Liite IX kappaleet I ja III/ Annex IX Chapters I and III

<b>ALLEKIRJOITUSOSIO SIGNATURE SECTION</b>	
<b>Tämä EU-vaatimustenmukaisuusvakuutus on annettu edellä mainitun laillisen valmistajan puolesta ja sen omalla, yksinomaisella vastuulla.</b>	
<b>Paikka</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Allekirjoitus/ Päivämäärä</b> <i>Signature/ Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nimi ja asema</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Sääntelyasiat

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**FRENCH**

<b>DÉCLARATION DE CONFORMITÉ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Nous, Cardinal Health 200 LLC, déclarons que les produits couverts par la présente déclaration de conformité de l'Union européenne satisfont à la disposition du règlement (UE) 2017/745 sur les dispositifs médicaux.
<b>Numéro de la déclaration de conformité</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Numéro de la documentation technique</b> <i>Technical Documentation Number</i>	RE00135119
<b>Nom du fabricant</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresse du fabricant</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Numéro d'enregistrement unique</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nom et adresse du représentant agréé</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nom et numéro d'identification de l'organisme notifié</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Numéro de certificat CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Catégorie de produit</b> <i>Product Category</i>	Thermomètres numériques sans contact Non-Contact Digital Thermometers
<b>UDI-DI de base</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Code, nom commercial et description du produit</b> <i>Product Code, Trade Name and Description</i>	Thermomètre tympanique et base 3TM 303013 – Genius 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Usage prévu</b> <i>Intended Purpose</i>	Le thermomètre tympanique et la base™ Genius 3 sont destinés à fournir des mesures de température à partir de la membrane tympanique.  The Genius™ 3 Tympanic Thermometer and Base is intended to


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<b>DÉCLARATION DE CONFORMITÉ</b> <i>DECLARATION OF CONFORMITY</i>	
	provide temperature measurements from the tympanic membrane.
<b>Classification et règle</b> <i>Classification and Rule</i>	Classification/ Classification: IIa Règle/ Rule: 10
<b>Caractéristiques communes</b> <i>Common Specifications</i>	Sans objet (N/A)
<b>Le cas échéant, ajouter la législation de l'Union européenne en vigueur</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Évaluation de la conformité</b> <i>Conformity Assessment</i>	Annexe IX, Chapitres I et III/ Annex IX Chapters I and III

<b>SECTION SIGNATURE</b> <i>SIGNATURE SECTION</i>	
<b>La présente déclaration de conformité de l'Union européenne est établie pour, au nom de et sous la seule responsabilité du fabricant légal identifié plus haut.</b>	
<b>Lieu de délivrance</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Signature/Date</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nom et fonction</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Affaires réglementaires

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**GERMAN**

<b>KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY</b>	
	<b>MDR:</b> Wir, Cardinal Health 200 LLC, erklären, dass die Produkte, die in dieser EU-Konformitätserklärung behandelt werden, den Bestimmungen der Medizinprodukteverordnung (EU) 2017/745 entsprechen.
<b>Nummer der Konformitätserklärung</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Technische Dokumentennummer</b> <i>Technical Documentation Number</i>	RE00135119
<b>Name des Herstellers</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresse des Herstellers</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Einzel-Registrierungsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Name und Adresse des bevollmächtigten Vertreters</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Name und Identifikationsnummer der benannten Stelle</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>CE-Zertifikat-Nummer</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Produktkategorie</b> <i>Product Category</i>	Kontaktlose Digitale Thermometer Non-Contact Digital Thermometers
<b>Grundlegende UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Produktcode, Handelsname und Beschreibung</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 tympanisches Thermometer und Basis 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Verwendungszweck</b> <i>Intended Purpose</i>	Das Genius™ 3 tympanische Thermometer und Basis ist für die Temperaturmessung am Trommelfell vorgesehen.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Klassifizierung und Richtlinie</b>	Klasse/ Classification: IIa


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<b>KONFORMITÄTSERKLÄRUNG DECLARATION OF CONFORMITY</b>	
<i>Classification and Rule</i>	Richtlinie/ Rule: 10
<b>Allgemeine Spezifikationen</b> <i>Common Specifications</i>	Nicht zutreffend (N/A)
<b>Gegebenenfalls anwendbare Rechtsvorschriften der Gewerkschaft hinzufügen</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Konformitätsbewertung</b> <i>Conformity Assessment</i>	Anhang IX Kapitel I und III/ Annex IX Chapters I and III

<b>UNTERSCHRIFTSABSCHNITT SIGNATURE SECTION</b>	
<b>Diese EU-Konformitätserklärung wird für und im Namen und unter der alleinigen Verantwortung des oben angegebenen rechtmäßigen Herstellers ausgestellt.</b>	
<b>Ausstellungsort</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Unterschrift /Datum</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Name und Funktion</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Zulassungsangelegenheiten

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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**GREEK**

<b>ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Εμείς, η Cardinal Health 200 LLC, δηλώνουμε ότι τα προϊόντα που καλύπτονται στην παρούσα Δήλωση συμμόρφωσης ΕΕ πληρούν τις διατάξεις του Κανονισμού (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα.
<b>Αριθμός δήλωσης συμμόρφωσης</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Αριθμός τεχνικού φακέλου</b> <i>Technical Documentation Number</i>	RE00135119
<b>Όνομα κατασκευαστή</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Διεύθυνση κατασκευαστή</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Ενιαίος αριθμός καταχώρισης</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Όνομα και αριθμός αναγνώρισης κοινοποιημένου οργανισμού</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Αριθμός πιστοποιητικού CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Κατηγορία προϊόντος</b> <i>Product Category</i>	Ανέπαφα ψηφιακά θερμόμετρα Non-Contact Digital Thermometers
<b>Βασικό UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Κωδικός προϊόντος, εμπορική επωνυμία και περιγραφή</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 Τυμπανικό θερμόμετρο και βάση 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Προοριζόμενος σκοπός</b> <i>Intended Purpose</i>	Το τυμπανικό θερμόμετρο και βάση Genius™ 3 προορίζεται να παρέχει μετρήσεις θερμοκρασίας από την τυμπανική μεμβράνη. The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Ταξινόμηση και κανόνας</b>	Κατηγορία/ Classification: ΙΙα


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<b>ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Classification and Rule</i>	Κανόνας/ Rule: 10
<b>Κοινές προδιαγραφές</b> <i>Common Specifications</i>	Δεν ισχύει (N/A)
<b>Όπου αρμόζει, προσθέστε την εφαρμοστέα νομοθεσία της Ένωσης</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Αξιολόγηση της συμμόρφωσης</b> <i>Conformity Assessment</i>	Παράρτημα IX Κεφάλαια I και III/ Annex IX Chapters I and III

<b>ΕΝΟΤΗΤΑ ΥΠΟΓΡΑΦΗΣ</b> <i>SIGNATURE SECTION</i>	
<p align="center"><b>Η παρούσα Δήλωση συμμόρφωσης ΕΕ εκδίδεται στο όνομα και για λογαριασμό και με την αποκλειστική ευθύνη του Νόμιμου κατασκευαστή που ταυτοποιείται παραπάνω.</b></p>	
<b>Τόπος έκδοσης</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Υπογραφή/Ημερομηνία</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Όνομα και λειτουργία</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Ρυθμιστικές υποθέσεις

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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**ITALIAN**

<b>DICHIARAZIONE DI CONFORMITÀ DECLARATION OF CONFORMITY</b>	
	<b>MDR:</b> Noi sottoscritti, Cardinal Health 200 LLC, dichiariamo che i prodotti relativi alla presente Dichiarazione di conformità UE sono conformi alle disposizioni del Regolamento sui dispositivi medici (UE) 2017/745.
<b>Numero della dichiarazione di conformità</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Numero di documentazione tecnica</b> <i>Technical Documentation Number</i>	RE00135119
<b>Nome del fabbricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Indirizzo del fabbricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Numero di registrazione unico</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nome e indirizzo del mandatario</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nome e numero di identificazione dell'organismo notificato</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Numero di certificato CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Categoria di prodotto</b> <i>Product Category</i>	Termometri digitali senza contatto Non-Contact Digital Thermometers
<b>UDI-DI di base</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Codice prodotto, denominazione commerciale e descrizione</b> <i>Product Code, Trade Name and Description</i>	303013 – Termometro timpanico e base Genius™ 3 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Destinazione d'uso</b> <i>Intended Purpose</i>	Il termometro timpanico e base Genius™ 3 ha lo scopo di fornire misurazioni della temperatura della membrana timpanica. The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Classificazione e regola</b> <i>Classification and Rule</i>	Classe/ Classification: IIa Regola/ Rule: 10


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<b>DICHIARAZIONE DI CONFORMITÀ</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Specifiche comuni</b> <i>Common Specifications</i>	Non applicabile (N/A)
<b>Ove necessario, aggiungere la legislazione pertinente dell'Unione</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Valutazione della conformità</b> <i>Conformity Assessment</i>	Allegato IX, Capitoli I e III/ Annex IX Chapters I and III

<b>SEZIONE FIRMA</b> <i>SIGNATURE SECTION</i>	
<b>La presente Dichiarazione di conformità UE è stata prodotta per, a nome e sotto esclusiva responsabilità del fabbricante legale sopra indicato.</b>	
<b>Luogo di rilascio</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Firma/Data</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nome e mansion</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Affari regolatori

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**NORWEGIAN**

<b>SAMSVARERKLÆRING</b> <i>DECLARATION OF CONFORMITY</i>	
 <b>CardinalHealth</b>	<b>MDR:</b> Vi, Cardinal Health 200 LLC, erklærer at produktene som dekkes i denne EU-samsvarerklæringen oppfyller bestemmelsene i forordningen om medisinsk utstyr (EU) 2017/745.
<b>Samsvarerklæringsnummer</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Teknisk dokumentasjonsnummer</b> <i>Technical Documentation Number</i>	RE00135119
<b>Produsentens navn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Produsentens adresse</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Enkeltregistreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Autorisert representants navn og adresse</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Teknisk kontrollorgans navn og identifikasjonsnummer</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>CE-sertifikatnummer</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Produktkategori</b> <i>Product Category</i>	Berøringsfrie digitale termometre Non-Contact Digital Thermometers
<b>Grunnleggende UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Produktkode, handelsnavn og beskrivelse</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 tympanisk termometer og sokkel 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Tiltenkt formal</b> <i>Intended Purpose</i>	Geniet™ 3 tympanisk termometer og sokkel er beregnet for å gi temperaturmålinger fra trommehinnen. The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Klassifisering og regel</b> <i>Classification and Rule</i>	Klasse/ Classification: IIa Regel/ Rule: 10


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<b>SAMSVARSERKLÆRING</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Vanlige spesifikasjoner</b> <i>Common Specifications</i>	Ikke relevant (N/A)
<b>Legg til gjeldende EU-lovgivning der det er relevant</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Samsvarsvurdering</b> <i>Conformity Assessment</i>	Tillegg IX, kapittel I og III/ Annex IX Chapters I and III

<b>SIGNATURDEL</b> <i>SIGNATURE SECTION</i>	
<b>Denne EU-samsvarserklæringen utstedes for og på vegne av den ovenfor identifiserte lomessige produsenten, og utelukkende under dennes ansvar.</b>	
<b>Utstedelsessted</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Signatur/Dato</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Navn og funksjon</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Juridisk avdeling

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**POLISH**

<b>DEKLARACJA ZGODNOŚCI</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> My, Cardinal Health 200 LLC, oświadczamy, że produkty objęte Deklaracją zgodności UE spełniają wymagania rozporządzenia w sprawie wyrobów medycznych (EU) 2017/745.
<b>Numer Deklaracji zgodności</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Numer dokumentacji technicznej</b> <i>Technical Documentation Number</i>	RE00135119
<b>Nazwa producenta</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adres producenta</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Pojedynczy numer rejestracyjny</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nazwa i adres autoryzowanego przedstawiciela</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nazwa i numer identyfikacyjny jednostki notyfikowanej</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Numer certyfikatu CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Kategoria produktuc</b> <i>Product Category</i>	Bezdotykowe termometry cyfrowe Non-Contact Digital Thermometers
<b>Podstawowy unikalny identyfikator urządzenia UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Kod produktu, nazwa handlowa i opis</b> <i>Product Code, Trade Name and Description</i>	303013 – Termometr bębenkowy i podstawa Genius™ 3 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Przeznaczenie</b> <i>Intended Purpose</i>	Termometr bębenkowy i podstawa Genius™ 3 są przeznaczone do pomiaru temperatury z błony bębenkowej.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.

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<b>DEKLARACJA ZGODNOŚCI</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Klasyfikacja i reguła</b> <i>Classification and Rule</i>	Klasa,/ Classification: IIa Reguła/ Rule: 10
<b>Wspólne specyfikacje</b> <i>Common Specifications</i>	Nie dotyczy (N/A)
<b>W stosownych przypadkach dodać obowiązujące przepisy unijne</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Ocena zgodności</b> <i>Conformity Assessment</i>	Załącznik IX, rozdziały I i III/ Annex IX Chapters I and III

<b>SEKCJA PODPISÓW</b> <i>SIGNATURE SECTION</i>	
Niniejsza deklaracja zgodności UE została wydana w imieniu i na wyłączną odpowiedzialność legalnego producenta określonego powyżej.	
<b>Miejsce wydania</b> <i>Place of Issue</i>	Waukegan, IL 60085 USA
<b>Podpis/Data</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Imię i nazwisko oraz stanowisko</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Dział spraw regulacyjnych

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**PORTUGUESE**

<b>DECLARAÇÃO DE CONFORMIDADE</b> <b>DECLARATION OF CONFORMITY</b>	
 <b>CardinalHealth</b>	<b>MDR:</b> Nos, Cardinal Health 200 LLC, declaramos que os produtos abrangidos por esta Declaração de Conformidade da UE cumprem a disposição do Regulamento relativo a dispositivos médicos (UE) 2017/745.
<b>Número de Declaração de Conformidade</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Número de documentação técnica</b> <i>Technical Documentation Number</i>	RE00135119
<b>Nome do fabricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Endereço do fabricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Número único de registo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nome e endereço do representante autorizado</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nome e número de identificação do organismo notificado</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Número do certificado CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Categoria do produto</b> <i>Product Category</i>	Termômetros digitais sem contato Non-Contact Digital Thermometers
<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Código, nome comercial e descrição do produto</b> <i>Product Code, Trade Name and Description</i>	303013 – Termómetro Timpânico e Base Genius™ 3 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Finalidade</b> <i>Intended Purpose</i>	O Termómetro Timpânico e Base Genius™ 3 destina-se a fornecer medições de temperatura a partir da membrana timpânica.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.


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<b>DECLARAÇÃO DE CONFORMIDADE</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Classificação e regra</b> <i>Classification and Rule</i>	Classe/ Classification: IIA Regra/ Rule: 10
<b>Especificações comuns</b> <i>Common Specifications</i>	Não aplicável (N/A)
<b>Se for o caso, adicione a legislação aplicável ao nível da União</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Avaliação de conformidade</b> <i>Conformity Assessment</i>	Anexo IX Capítulos I e III/ Annex IX Chapters I and III

<b>SECÇÃO DE ASSINATURA</b> <i>SIGNATURE SECTION</i>	
<b>Esta Declaração de Conformidade da UE é emitida em nome e sob a responsabilidade exclusiva do Fabricante legal identificado acima.</b>	
<b>Local de emissão</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Assinatura/Data</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nome e cargo</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Assuntos Regulamentares

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**ROMANIAN**

<b>DECLARAȚIE DE CONFORMITATE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Noi, Cardinal Health 200 LLC, declarăm că produsele acoperite în această Declarație de conformitate UE respectă prevederile Regulamentului privind dispozitivele medicale (UE) 2017/745.
<b>Număr declarație de conformitate</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Număr documentație tehnică</b> <i>Technical Documentation Number</i>	RE00135119
<b>Numele producătorului</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa producătorului</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Număr unic de înregistrare</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Numele și adresa reprezentantului autorizat</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Numele și numărul de identificare al Organismului notificat</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Numărul certificatului CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Categoria de produs</b> <i>Product Category</i>	Termometre digitale fără contact Non-Contact Digital Thermometers
<b>UDI-DI de bază</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Cod produs, Nume comercial și Descriere</b> <i>Product Code, Trade Name and Description</i>	Termometru timpanic și bază 303013 - Genius™ 3 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Destinația utilizării</b> <i>Intended Purpose</i>	Termometrul timpanic și baza Genius™ 3 sunt destinate să furnizeze măsurători de temperatură de la nivelul membranei timpanice.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Clasificare și regulă</b>	Clasă/ Class: IIa


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<b>DECLARAȚIE DE CONFORMITATE</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Classification and Rule</i>	Regulă/ Rule: 10
<b>Specificații commune</b> <i>Common Specifications</i>	Nu este cazul (N/A)
<b>Când este cazul, adăugați legislația aplicabilă din Uniune</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Evaluarea de conformitate</b> <i>Conformity Assessment</i>	Anexa IX, Capitolele I și III/ Annex IX Chapters I and III

<b>SECȚIUNEA DE SEMNĂTURI</b> <i>SIGNATURE SECTION</i>	
<b>Această Declarație de conformitate UE este emisă în numele și sub responsabilitatea exclusivă a Producătorului Legal identificat mai sus.</b>	
<b>Locul emiterii</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Semnătura/Data</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nume și funcție</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Afaceri de reglementare

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**SLOVAK**

<b>VYHLÁSENIE O ZHODE DECLARATION OF CONFORMITY</b>	
 <b>CardinalHealth</b>	<b>MDR:</b> Vyhlasujeme, Cardinal Health 200 LLC, že produkty uvedené v tomto vyhlásení o zhode EÚ spĺňajú ustanovenia nariadenia o zdravotníckych pomôckach (EÚ) 2017/745.
<b>Číslo vyhlásenia o zhode</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Číslo technickej dokumentácie</b> <i>Technical Documentation Number</i>	RE00135119
<b>Názov výrobcu</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Adresa výrobcu</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Jednotné registračné číslo</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Meno a adresa oprávneného zástupcu</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Meno a identifikačné číslo informovaného orgánu</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Číslo certifikátu CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Kategória výrobku</b> <i>Product Category</i>	Digitálne teplomery bez kontaktu Non-Contact Digital Thermometers
<b>Základné UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Kód výrobku, obchodný názov a popis</b> <i>Product Code, Trade Name and Description</i>	303013 – Tympanický teplomer a základňa Genius™ 3 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Zamýšľaný účel</b> <i>Intended Purpose</i>	Tympanický teplomer a základňa Genius™ 3 sú určené na meranie teploty z tympanickej membrány.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Klasifikácia a pravidlo</b>	Trieda/ Class: IIa


<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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<b>VYHLÁSENIE O ZHODE</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Classification and Rule</i>	Pravidlo/ Rule: 10
<b>Bežné špecifikácie</b> <i>Common Specifications</i>	Nevzťahuje sa (N/A)
<b>V prípade potreby doplňte príslušné právne predpisy Únie</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Posúdenie zhody</b> <i>Conformity Assessment</i>	Príloha IX, kapitoly I a III/ Annex IX Chapters I and III

<b>PODPISOVÁ SEKCIA</b> <i>SIGNATURE SECTION</i>	
<b>Toto vyhlásenie o zhode EÚ sa vydáva pre zákonného výrobcu, v jeho mene a na jeho výhradnú zodpovednosť.</b>	
<b>Miesto vydania</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Podpis/ Dátum</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Meno a pozícia</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Regulačné záležitosti

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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**SPANISH**

<b>DECLARACIÓN DE CONFORMIDAD</b> <i>DECLARATION OF CONFORMITY</i>	
 <b>CardinalHealth</b>	<b>MDR:</b> Nosotros, Cardinal Health 200 LLC, declaramos que los productos contemplados en la presente Declaración de conformidad de la UE cumplen con la disposición del Reglamento sobre productos sanitarios (UE) 2017/745.
<b>Número de declaración de conformidad</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Número de documentación técnica</b> <i>Technical Documentation Number</i>	RE00135119
<b>Nombre del fabricante</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Dirección del fabricante</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Número de registro único</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Nombre y dirección del representante autorizado</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Nombre y número de identificación del organismo notificado</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Número de certificado CE</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Categoría del product</b> <i>Product Category</i>	Termómetros digitales sin contacto Non-Contact Digital Thermometers
<b>UDI-DI básico</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Código del producto, nombre comercial y descripción</b> <i>Product Code, Trade Name and Description</i>	303013, termómetro timpánico Genius™ 3 con base 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Propósito</b> <i>Intended Purpose</i>	El termómetro timpánico Genius™ 3 con base está diseñado para proporcionar mediciones de temperatura desde la membrana timpánica.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.


<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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<b>DECLARACIÓN DE CONFORMIDAD</b> <i>DECLARATION OF CONFORMITY</i>	
<b>Clasificación y regla</b> <i>Classification and Rule</i>	Clase/ Class: IIa Regla/ Rule: 10
<b>Especificaciones comunes</b> <i>Common Specifications</i>	No corresponde (N/A)
<b>Cuando proceda, añada la legislación de la Unión Europea aplicable</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Evaluación de conformidad</b> <i>Conformity Assessment</i>	Anexo IX capítulos I y III/ Annex IX Chapters I and III

<b>SECCIÓN DE FIRMA</b> <i>SIGNATURE SECTION</i>	
<b>La presente Declaración de conformidad de la UE se emite para y en nombre de y bajo la responsabilidad exclusiva del fabricante que se identificó anteriormente.</b>	
<b>Lugar de emisión</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Firma / Fecha</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Nombre y función</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Asuntos normativos

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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**SWEDISH**

<b>FÖRSÄKRAN OM ÖVERENSSTÄMMELSE</b> <i>DECLARATION OF CONFORMITY</i>	
	<b>MDR:</b> Vi, Cardinal Health 200 LLC, försäkrar härmed att produkterna som omfattas av denna EU-försäkran om överensstämmelse uppfyller bestämmelserna om medicintekniska produkter i förordning (EU) 2017/745.
<b>Nummer på försäkran om överensstämmelse</b> <i>Declaration of Conformity Number</i>	RE00184748
<b>Nummer på teknisk documentation</b> <i>Technical Documentation Number</i>	RE00135119
<b>Tillverkarens namn</b> <i>Manufacturer's Name</i>	Cardinal Health 200, LLC
<b>Tillverkarens address</b> <i>Manufacturer's Address</i>	3651 Birchwood Drive Waukegan, IL 60085 USA
<b>Unikt registreringsnummer</b> <i>Single Registration Number</i>	US-MF-000006765
<b>Namn på auktoriserad representant och address</b> <i>Authorized Representative's Name and Address</i>	Cardinal Health Ireland Manufacturing Limited, Tullamore Business & Technology Park R35 H903, Tullamore, County Offaly, Ireland
<b>Namn på anmält organ och identifikationsnummer</b> <i>Notified body's Name and Identification Number</i>	TÜV SÜD Product Service GmbH Ridlerstraße 65 D-80339 München, Germany Identification Number: 0123
<b>Nummer på CE-certifikat</b> <i>CE Certificate Number</i>	G10 056759 0040 Rev.00
<b>Produktkategori</b> <i>Product Category</i>	Beröringsfria digitala termometrar Non-Contact Digital Thermometers
<b>Grundläggande UDI-DI</b> <i>Basic UDI-DI</i>	063014000000000000001566L
<b>EMDN</b>	V0301010202
<b>Produktkod, handelsnamn och beskrivning</b> <i>Product Code, Trade Name and Description</i>	303013 – Genius™ 3 Tympanisk termometer och bas 303013 – Genius™ 3 Tympanic Thermometer and Base
<b>Avsedd användning</b> <i>Intended Purpose</i>	Genius™ 3 Tympanisk termometer och bas är avsedd för temperaturmätningar på trumhinnan.  The Genius™ 3 Tympanic Thermometer and Base is intended to provide temperature measurements from the tympanic membrane.
<b>Klassificering och regel</b>	Klass/ Class: IIa

<b>DOCUMENT NO:</b>	RE00184748	<b>REVISION:</b>	1
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<b>FÖRSÄKRAN OM ÖVERENSSTÄMMELSE</b> <i>DECLARATION OF CONFORMITY</i>	
<i>Classification and Rule</i>	Regel/ Rule: 10
<b>Gemensamma specifikationer</b> <i>Common Specifications</i>	Ej tillämpligt (N/A)
<b>Lägg till tillämplig EU-lagstiftning</b> <i>Where appropriate, add applicable Union legislation</i>	RoHS 2015/863 REACH 1907/2006
<b>Bedömning av överensstämmelse</b> <i>Conformity Assessment</i>	Bilaga IX kapitel I och III/ Annex IX Chapters I and III

<b>SEKTION FÖR UNDERSKRIFT</b> <i>SIGNATURE SECTION</i>	
<b>Denna EU-försäkran om överensstämmelse utfärdas för och på uppdrag av och under eget ansvar av den juridiska tillverkaren som anges ovan.</b>	
<b>Plats för utfärdande</b> <i>Place of Issue</i>	<b>Waukegan, IL 60085 USA</b>
<b>Underskrift/ Datum</b> <i>Signature/Date</i>	<i>Soumitra Shilotri</i> <small>Electronically signed by: Soumitra Shilotri Reason: Author Date: Apr 24, 2024 16:46 EDT</small>
<b>Namn och function</b> <i>Name and Function</i>	Soumitra Shilotri Regulatory Affairs Myndighetsärenden







# Document to be digitally signed'

Final Audit Report

2024-04-24

Created:	2024-04-24
By:	Soumitra Shilotri (soumitra.shilotri@cardinalhealth.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAACNBqw4IIPyOZMCYBHWm8bdf1ACn9JT60

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Signature Date: 2024-04-24 - 8:46:28 PM GMT - Time Source: server- IP address: 137.83.250.2
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