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Smith+Nephew

Document Number:	DOC-ARTC-TF-005
Revision:	B
PLM Ref#	RIMSYS CERT-27602

EUROPEAN DECLARATION OF CONFORMITY[1]

Declaration confirms that the product listed below meets: Regulations 2017/745, and is issued under the sole responsibility of Smith & Nephew/ Arthrocare Corporation.[2]

Manufacturer's Name[3]	ArthroCare Corporation
Business Address[4]	ArthroCare Corporation 7000 West William Cannon Drive Austin, TX 78735 USA
Single Registration Number (SRN) [5]	US-MF-000017581
European Authorised Representative[6]	Smith & Nephew Operations B.V.
Business Address[7]	Bloemlaan 2 2132 NP Hoofddorp Netherlands
Single Registration Number (SRN) [5]	NL-AR-000012769
Product Name[8]:	RAPID RHINO™ RAPID PAC, RAPID RHINO™ Epistaxis Device, RAPID RHINO™ Nasal Catheter Anterior / Posterior Epistaxis, RAPID RHINO™ Nasal Sinus Dressings
Intended Use[9]	**RAPID RHINO™ RAPID PAC:** **The RAPID RHINO™ RAPID PAC epistaxis device is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity.** **RAPID RHINO™ Epistaxis Device:** **The RAPID RHINO™ epistaxis device is an inflatable balloon with CMC hydrogel coating intended to assist in the control of Internal nasal bleeding by exerting pressure against the sphenopalatine artery.** **RAPID RHINO™ Nasal Catheter Anterior / Posterior Epistaxis:** **The RAPID RHINO™ 900 epistaxis device consisting of an inflatable balloon is intended to control internal nasal bleeding by exerting pressure against the sphenopalatine artery.** **RAPID RHINO™ Nasal Sinus Dressings:** RAPID RHINO™ Nasal Sinus dressing is a device consisting of foam intended to minimize bleeding through filling out the nasal chamber.

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Electrical and Electronic Equipment (EEE) Statement[29]	N/A
Concerning Batteries and Waste Batteries Statement[30]	N/A
Conformity Assessment Procedure (Annex)[10]	Annex IX
Notified Body Name[11]	TUV SUD Product Service GmbH
Notified Body Number[12]	CE 0123
Verification Certificate(s)[13]	G15 077112 0053 Rev. 01

Signed on behalf of[14] Smith & Nephew/Arthrocare Corporation	
Signature[15]	Signed by: Signer Name: Piedad Pena Signing Reason: I approve this document Signing Time: 06-Oct-2026 | 16:30:49 BST 5D46F116173D4FFFA4A7648880EAC17F
Name[16]	Piedad Pena
Position[17]	Senior Manager Regulatory Affairs Sports Medicine, Coblation and ENT
Date[18]	06 October 2026
Location[19]	Austin, TX
Declaration of Conformity Reference[20]	DOC-ARTC-TF-005

Product Schedule[21]

Product Code / Catalogue Number[22]	Product Description or Product Variant[23]	Risk Classification[24]	Basic UDI[25]
RR 300	3CM RIEMANN NASAL DRESSING	Class IS	0885556SN000153LQ

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RR 400	4CM RIEMANN NASAL DRESSING	Class IS	0885556SN000153LQ
RR 450	4.5CM ANTERIOR	Class IS	0885556SN000154LS
RR 500	5.5CM GOODMAN NASAL DRESSING	Class IS	0885556SN000153LQ
RR 800	8CM NASAL DRESSING	Class IS	0885556SN000153LQ
RR 530	5.5CM RAPID PAC ANTERIOR	Class IS	0885556SN000154LS
RR 550	5.5CM ANTERIOR	Class IS	0885556SN000154LS
RR 551	5.5CM LUMEN ANTERIOR	Class IS	0885556SN000154LS
RR 750	7.5CM ANTERIOR/POSTERIO	Class IS	0885556SN000154LS
RR 751	7.5CM LUMEN ANTERIOR/POSTERIO	Class IS	0885556SN000154LS
RR 900	9CM ANTERIOR/POSTERIOR DUAL	Class IS	0885556SN000154LS

Standards / Common Specification(s)[26]:		
EN ISO 13485:2016+A11:2021	EN ISO 14971:2019+A11:2021	EN 62366-1:2015+A1:2020
EN ISO 15223-1:2021+A1:2025	ISO 20417:2021	ISO 10993-1:2018
ISO 10993-5:2009 (2017)	ISO 10993-6: 2016	ISO 10993-7: 2008/Amd 1:2019
ISO 10993-10:2021	ISO 10993-11:2017	ISO 10993-12:2021
ISO 10993-17:2023	ISO 10993-18:2020+A1:2022	ISO 10993-23:2021
EN 556-1: 2001/AC:2006	EN ISO 11607-1:2020 + A11:2022	EN ISO 11607-2:2020 +A1:2023
EN ISO 11737-1:2018+A1:2021	EN ISO 11737-2:2020	ISO 11135:2014/Amd 1:2018
ASTM D4332:2-Jun-22	ASTM D4169:2023 e1	ASTM F88/F88M:2023
ASTM F1140/F1140M:(R2020)	ASTM F2096:2011(2019)	ASTM F1886/F1886M:2016
ASTM F1929:2023	ASTM F3039:2023	MEDDEV 2.7.1: 2016 (Rev. 4)
ISTA 3A: March 2018		

Intended Use European Language Translations[27]:

Language[28]		Code	Intended Use
EN	**Local**		
Bulgarian	български език	BG	Изделието за епистаксис RAPID RHINO™ RAPID PAC е предназначено за свеждане до минимум на кървенето и отока и за предотвратяване на сраствания между септума и носната кухина. Устройството за епистаксис RAPID RHINO™ е надуваем балон с покритие от CMC хидрогел, предназначен да подпомогне контрола на вътрешното назално кървене чрез упражняване на натиск върху сфенопалатин артерията.

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			Устройството за епистаксис RAPID RHINO™ 900, състоящо се от надуваем балон, е предназначено за контрол на вътрешно назално кървене чрез упражняване на натиск върху сфенопалатиновата артерия. Назалната синусова превръзка RAPID RHINO™ е изделие, състоящо се от пяна, предназначено да сведе до минимум кървенето чрез запълване на носната камера.
Croatian	Hrvatski	HR	Uređaj za epistaksiju RAPI RHINO™ RAPID PAC namijenjen je smanjivanju krvarenja i edema te sprječavanju adhezija između septuma i nosne šupljine. Uređaj za epistaksiju RAPID RHINO™ balon je koji se može napuhati s CMC hidrogelnim premazom koji pomaže u kontroli unutarnjeg nazalnog krvarenja primjenom pritiska na arteriju sfenopalatinu. Uređaj za epistaksiju RAPID RHINO™ 900 koji se sastoji od balona koji se može napuhati namijenjen je za kontrolu unutarnjeg nazalnog krvarenja primjenom pritiska na arteriju sfenopalatinu. Obloga za nosne sinuse RAPID RHINO™ uređaj je koji se sastoji od pjene namijenjene smanjivanju krvarenja ispunjavanjem nosne komore.
Czech	Český Jazyk	CZ	Prostředek pro epistaxi RAPID RHINO™ RAPID PAC je určen k minimalizaci krvácení a edému a k prevenci srůstů mezi septem a nosní dutinou. Prostředek pro epistaxi RAPID RHINO™ je nafukovací balónek s hydrogelovým povlakem CMC, který má pomoci při kontrole vnitřního nosního krvácení působením tlaku na tepnu sfenopalatinu. Prostředek pro epistaxi RAPID RHINO™ 900 sestávající z nafukovacího balónku je určen ke kontrole vnitřního nosního krvácení působením tlaku na tepnu sfenopalatinu. Nosní a sinusové krytí RAPID RHINO™ je prostředek skládající se z pěny určené k minimalizaci krvácení díky vyplnění nosní komory.
Danish	Dansk	DK	RAPID RHINO™ RAPID PAC epistaxisanordning er beregnet til at minimere blødning og ødem og til at

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			forebygge adhæsioner mellem septum og næsehule. RAPID RHINO™ epistaxisanordningen er en oppustelig ballon med CMC hydrogelbelægning, der er beregnet til hjælpe med at kontrollere indre næseblødning ved at udøve tryk mod sphenopalatinarterien. RAPID RHINO™ 900 epistaxis-anordningen, der består af en oppustelig ballon, er beregnet til at kontrollere indre næseblødning ved at udøve tryk mod sphenopalatinarterien. RAPID RHINO™ nasal sinusforbinding er en anordning, der består af skum, der er beregnet til at minimere blødning ved at fylde næsekammeret.
Dutch	Nederlands	NL	Het RAPID RHINO™ RAPID PAC-neusbloedingenhulpmiddel is bedoeld om bloedingen en zwellingen tot een minimum te beperken en adhesies tussen het septum en de neusholte te voorkomen. Het RAPID RHINO™-neusbloedingenhulpmiddel is een opblaasbare ballon met CMC-hydrogelcoating die is bedoeld om te helpen bij de beheersing van inwendige neusbloedingen door druk uit te oefenen tegen de sfenopalatineslagader. Het RAPID RHINO™ 900-neusbloedingenhulpmiddel bestaat uit een opblaasbare ballon en is bedoeld om inwendige neusbloedingen onder controle te houden door druk uit te oefenen tegen de sfenopalatineslagader. RAPID RHINO™-neussinusverband is een hulpmiddel dat bestaat uit schuim dat bedoeld is om bloeding tot een minimum te beperken door de neuskamer te vullen.
Estonian	Eesti	EE	Epistaksisseade RAPID RHINO™ RAPID PAC on ette nähtud veritsuse ja turse minimeerimiseks ning vaheseina ja ninaõõne vaheliste liidete vältimiseks. Epistaksisseade RAPID RHINO™, mis koosneb CMC hüdrogeelkattega täidetavast balloonist, on mõeldud sisemise ninaverejooksu kontrollimiseks, avaldades survet fenopalatiinarterile. Epistaksisseade RAPID RHINO™ 900, mis koosneb täidetavast balloonist, on mõeldud sisemise

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			ninaverejooksu kontrollimiseks, avaldades survet fenopalatiinarterile. RAPID RHINO™ vahust koosnev nasaalne siinusside on seade, mis on mõeldud verejooksu minimeerimiseks ninaõõnte täitmise kaudu.
Finnish	Suomi	FI	RAPID RHINO™ RAPID PAC -epistaksislaite on tarkoitettu verenvuodon ja turvotuksen minimointiin sekä väliseinän ja nenäontelon välisten kiinnikkeiden estämiseen. RAPID RHINO™ -epistaksislaite on täytettävä pallo, jossa on CMC-hydrogeelipinnoite. Se on tarkoitettu helpottamaan sisäisen nenäverenvuodon hallintaa painamalla kitalaen-suulaen valtimoa. Täytettävästä pallosta koostuva RAPID RHINO™ 900 -epistaksislaite on tarkoitettu sisäisen nenäverenvuodon hallintaan kohdistamalla painetta kitalaen-suulaen valtimoon. RAPID RHINO™ -nenäontelosidos on vaahtomuovista valmistettu laite, joka on tarkoitettu verenvuodon minimointiin nenäonteloa täytettäessä.
French	Français	FR	Le dispositif pour épistaxis RAPID RHINO™ RAPID PAC est destiné à réduire au maximum les saignements et les oedèmes et à prévenir les adhérences entre le septum et la cavité nasale. Le dispositif pour épistaxis RAPID RHINO™ est un ballonnet gonflable avec revêtement d'hydrogel CMC destiné à aider au contrôle des saignements nasaux internes en exerçant une pression sur l'artère sphéno-palatine. Le dispositif pour épistaxis RAPID RHINO™ 900 composé d'un ballonnet gonflable est destiné à contrôler les saignements nasaux internes en exerçant une pression sur l'artère sphéno-palatine. Le pansement pour sinus nasal RAPID RHINO™ est un dispositif composé de mousse destiné à réduire au maximum le saignement en remplissant la cavité nasale.
German	Deutsch	DE	Die RAPID RHINO™ RAPID PAC Epistaxis-Tamponade ist dazu bestimmt, Blutungen und Ödeme zu minimieren und Adhäsionen zwischen dem Septum und der Nasenhöhle zu verhindern.

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			Die RAPID RHINO™ Epistaxis-Tamponade ist ein aufblasbarer Ballon mit CMC-Hydrogelbeschichtung, der dazu bestimmt ist, die Kontrolle innerer Nasenblutungen durch Druckausübung auf die Arteria sphenopalatina zu unterstützen. Die RAPID RHINO™ 900 Epistaxis-Tamponade, die aus einem aufblasbaren Ballon besteht, ist dazu bestimmt, innere Nasenblutungen durch Druckausübung auf die Arteria sphenopalatina zu kontrollieren. RAPID RHINO™ Nasen-Sinus-Tamponade ist ein aus Schaum bestehendes Produkt, das dazu bestimmt ist, Blutungen durch Ausfüllen der Nasenkammer zu minimieren.
Greek	Ελληνικά	GR	Το τεχνολογικό προϊόν επίσταξης RAPID RHINO™ RAPID PAC προορίζεται για την ελαχιστοποίηση της αιμορραγίας και του οιδήματος και για την πρόληψη της δημιουργίας συμφύσεων μεταξύ του διαφράγματος και της ρινικής κοιλότητας. Το τεχνολογικό προϊόν επίσταξης RAPID RHINO™ είναι ένα διογκούμενο μπαλόνι με επικάλυψη υδρογέλης από CMC που προορίζεται για την υποβοήθηση του ελέγχου της εσωτερικής ρινικής αιμορραγίας ασκώντας πίεση στην σφηνοϋπερώια αρτηρία. Το τεχνολογικό προϊόν επίσταξης RAPID RHINO™ 900 που αποτελείται από ένα διογκούμενο μπαλόνι προορίζεται για τον έλεγχο της εσωτερικής ρινικής αιμορραγίας ασκώντας πίεση στην σφηνοϋπερώια αρτηρία. Το επίθεμα ρινικού κόλπου RAPID RHINO™ είναι ένα τεχνολογικό προϊόν που αποτελείται από αφρό και προορίζεται για την ελαχιστοποίηση της αιμορραγίας μέσω της πλήρωσης του ρινικού κόλπου.
Hungarian	Magyar	HU	A RAPID RHINO™ RAPID PAC orrvérzés-csillapító eszköz rendeltetése szerint a vérzés és az ödéma minimalizálására, valamint a szeptum és az orrüreg közötti adhéziók megelőzésére szolgál. A RAPID RHINO™ orrvérzés-csillapító eszköz CMC-hidrogél bevonattal rendelkező feltölthető ballon, amely a belső orrvérzés kontrollálásának elősegítésére szolgál azáltal, hogy nyomást gyakorol az arteria sphenopalatine-ra.

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			A RAPID RHINO™ 900 orrvérzés-csillapító eszköz, amely egy felfújható ballonból áll, a belső orrvérzés csillapítására szolgál az orrmelléküreg artériájára gyakorolt nyomás révén. A RAPID RHINO™ orrmelléküreg-kötszer egy olyan habból álló eszköz, amelynek célja a vérzés minimalizálása az orrüreg feltöltése révén.
Italian	Italiano	IT	A RAPID RHINO™ RAPID PAC orrvérzés-csillapító eszköz rendeltetése szerint a vérzés és az ödéma minimalizálására, valamint a szeptum és az orrüreg közötti adhéziók megelőzésére szolgál. A RAPID RHINO™ orrvérzés-csillapító eszköz CMC-hidrogél bevonattal rendelkező feltölthető ballon, amely a belső orrvérzés kontrollálásának elősegítésére szolgál azáltal, hogy nyomást gyakorol az arteria sphenopalatine-ra. A RAPID RHINO™ 900 orrvérzés-csillapító eszköz, amely egy felfújható ballonból áll, a belső orrvérzés csillapítására szolgál az orrmelléküreg artériájára gyakorolt nyomás révén. La medicazione per seni nasali RAPID RHINO™ è un dispositivo costituito da schiuma che serve a ridurre al minimo il sanguinamento attraverso il riempimento della camera nasale.
Latvian	Latviešu	LV	RAPID RHINO™ RAPID PAC deguna asiņošanas ierīce ir paredzēta, lai samazinātu asiņošanu un tūsku un novērstu saaugumus starp starpsienu un deguna dobumu. RAPID RHINO™ deguna asiņošanas ierīce ir piepūšams balons ar CMC hidrogēla pārklājumu, kas paredzēts, lai palīdzētu kontrolēt deguna iekšējo asiņošanu, radot spiedienu uz sfenopalatīna artēriju. RAPID RHINO™ 900 deguna asiņošanas ierīce, kas sastāv no piepūšama balona, ir paredzēta, lai kontrolētu iekšējo deguna asiņošanu, radot spiedienu uz sfenopalatīna artēriju. RAPID RHINO™ deguna blakusdobumu pārsējs ir ierīce, kas sastāv no putām, kas paredzētas asiņošanas mazināšanai, piepildot deguna kameru.
Lithuanian	Lietuvių	LT	RAPID RHINO™ RAPID PAC kraujavimo iš nosies stabdymo priemonė skirta kraujavimui ir edemai

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			kuo labiau sumažinti bei užkirsti kelią sąaugų susidarymui tarp nosies pertvaros ir nosies ertmės. RAPID RHINO™ kraujavimo iš nosies stabdymo priemonė yra pripučiamas balionėlis su CMC hidrogelio danga, padedantis kontroliuoti vidinį kraujavimą iš nosies, užspausdamas pleištinę gomurio arteriją. RAPID RHINO™ 900 kraujavimo iš nosies stabdymo priemonė, kurią sudaro pripučiamas balionėlis, yra skirta vidiniam nosies kraujavimui kontroliuoti, užspaudžiant pleištinę gomurio arteriją. RAPID RHINO™ nosies sinusų tvarstis yra iš porolono sudaryta priemonė, skirta kraujavimui kuo labiau sumažinti užpildant nosies ertmę.
Polish	Polski	PL	Wyrób do tamowania krwawień z nosa RAPID RHINO™ RAPID PAC jest przeznaczony do minimalizowania krwawienia i obrzęku oraz zapobiegania zrostom między przegrodą a jamą nosową. Wyrób do tamowania krwawień z nosa RAPID RHINO™ składający się z napełnianego balonika z powłoką hydrożelową CMC jest przeznaczony do wspomagania kontrolowania wewnętrznego krwawienia z jamy nosowej poprzez wywieranie nacisku na tętnicę klinowo-podniebienną. Wyrób do tamowania krwawień z nosa RAPID RHINO™ 900 składający się z napełnianego balonika jest przeznaczony do kontrolowania krwawienia z jamy nosowej poprzez wywieranie nacisku na tętnicę klinowo-podniebienną. Opatrunek RAPID RHINO™ do zatok nosowych to wyrób składający się z pianki, który ma na celu zminimalizowanie krwawienia przez wypełnienie komory nosowej.
Portuguese	Português	PT	O dispositivo para epistaxe RAPID RHINO™ RAPID PAC destina-se a minimizar a ocorrência de hemorragia e edema, e evitar aderências entre o septo e a cavidade nasal. O dispositivo de epistaxe RAPID RHINO™ é um balão insuflável com revestimento de hidrogel CMC destinado a auxiliar no controlo da hemorragia nasal interna, exercendo pressão contra a artéria esfenopalatina.

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			O dispositivo de epistaxe RAPID RHINO™ 900 constituído por um balão insuflável destina-se a controlar a hemorragia nasal interna, exercendo pressão contra a artéria esfenopalatina. O penso nasal RAPID RHINO™ é um dispositivo composto por espuma que se destina a minimizar a hemorragia através do preenchimento da câmara nasal.
Romanian	Română	RO	Dispozitivul pentru epistaxis RAPID RHINO™ RAPID PAC este destinat reducerii la minimum a sângerării și a edemului și prevenirii aderențelor dintre sept și cavitatea nazală. Dispozitivul pentru epistaxis RAPID RHINO™ este un balon gonflabil cu înveliș de hidrogel din CMC, destinat facilitării controlului sângerării nazale interne prin exercitarea presiunii asupra arterei sfenopalatine. Dispozitivul pentru epistaxis RAPID RHINO™ 900, constând dintr-un balon gonflabil, este destinat controlului sângerării nazale interne prin exercitarea presiunii asupra arterei sfenopalatine. Pansamentul nazal și sinusal RAPID RHINO™ este un dispozitiv format din spumă, destinat să reducă la minimum sângerarea prin umplerea cavității nazale.
Slovak	Slovenčina	SK	Pomôcka na epistaxu RAPID RHINO™ RAPID PAC je určená na minimalizáciu krvácania a edému a na predchádzanie adhéziám medzi septom a nosovou dutinou. Pomôcka na epistaxu RAPID RHINO™ je nafukovací balónik s hydrogélovou CMC vrstvou, ktorý je určený na pomoc pri regulácii vnútorného nosového krvácania tlakom vyvíjaným na klinovopodnebnú tepnu. Pomôcka na epistaxu RAPID RHINO™ 900 pozostávajúca z nafukovacieho balónika je určená na reguláciu vnútorného nosového krvácania tlakom vyvíjaným na klinovopodnebnú tepnu. Obklad nosových dutín RAPID RHINO™ je pomôcka pozostávajúca z peny, ktorá je určená na minimalizáciu krvácania prostredníctvom vyplnenia nosovej komory.

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Slovenian	Slovenščina	SI	Pripomoček za epistakso RAPID RHINO™ RAPID PAC je namenjen za zmanjšanje krvavitve in edema ter preprečevanje adhezij med septumom in nosno votlino. Pripomoček za epistakso RAPID RHINO™ je napihljiv balon s hidrogelno prevleko iz CMC, namenjen za pomoč pri nadzoru notranje nosne krvavitve z izvajanjem pritiska na sfenopalatinsko arterijo. Pripomoček za epistakso RAPID RHINO™ 900, sestavljen iz napihljivega balona, je namenjen za nadzor notranje nosne krvavitve z izvajanjem pritiska na sfenopalatinsko arterijo. Nosna obloga za sinus RAPID RHINO™ je pripomoček iz pene, namenjen zmanjševanju krvavitve z zapolnitvijo nosne votline.
Spanish	Español	ES	El dispositivo de epistaxis RAPID RHINO™ RAPID PAC está diseñado para reducir al mínimo el sangrado y los edemas y para prevenir adherencias entre el tabique nasal y la cavidad nasal. El dispositivo de epistaxis RAPID RHINO™ es un balón inflable con revestimiento de hidrogel CMC diseñado para ayudar a controlar el sangrado nasal interno ejerciendo presión contra la arteria esfenopalatina. El dispositivo de epistaxis RAPID RHINO™ 900, que consta de un balón inflable, está diseñado para controlar el sangrado nasal interno ejerciendo presión contra la arteria esfenopalatina. El apósito nasosinusal RAPID RHINO™ es un dispositivo compuesto de espuma diseñado para minimizar el sangrado rellenando la cavidad nasal.
Swedish	Svenska	SE	RAPID RHINO™ RAPID PAC epistaxis-enhet är avsedd att minimera blödning och ödem och för att förhindra adherenser mellan septum och näshålan. RAPID RHINO™ epistaxis-enhet är en fyllningsbar ballong med CMC-hydrogelbeläggning avsedd att hjälpa till vid kontrollen av inre näsblödning genom att utöva tryck mot arteria sphenopalatina. RAPID RHINO™ 900 epistaxis-enhet består av en fyllningsbar ballong som är avsedd för att

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			kontrollera inre näsblödning genom att utöva tryck mot arteria sphenopalatina. RAPID RHINO™ 900 epistaxis-enhet består av en fyllningsbar ballong som är avsedd för att kontrollera inre näsblödning genom att utöva tryck mot arteria sphenopalatina.

Electrical and Electronic Equipment (EEE) Statement[29] European Language Translations:

Language[28]		Code	Electrical and Electronic Equipment (EEE) Statement
EN	Local		
Bulgarian	български език	BG	Обектът на декларацията, описан по-долу, е в съответствие с Директива (ЕС) 2015/863 относно ограничението за употребата на определени опасни вещества в електрическото и електронното оборудване.
Croatian	Hrvatski	HR	Predmet deklaracije navedene u nastavku u skladu je s Direktivom (EU) 2015/863 ograničenju uporabe određenih opasnih tvari u električnoj i elektroničkoj opremi.
Czech	Český Jazyk	CZ	Předmět, jehož se týká níže uvedené prohlášení, je v souladu se směrnicí (EU) 2015/863 ohledně omezeného používání určitých nebezpečných látek v elektrických a elektronických zařízeních.
Danish	Dansk	DK	Formålet med nedenstående erklæring stemmer overens med direktiv (EU) 2015/863 ombegrænsning af anvendelsen af visse farlige stoffer i elektrisk og elektronisk udstyr.
Dutch	Nederlands	NL	Het onderwerp van de hieronder beschreven verklaring is in overeenstemming met richtlijn (EU) 2015/863 betreffende beperking van het gebruik van bepaalde gevaarlijke stoffen in elektrische en elektronische apparatuur.
Estonian	Eesti	EE	Allkirjeldatud deklareeritav toode on kooskõlas direktiiviga (EL) 2015/863, mis käsitleb teatavate ohtlike ainete kasutamise piiramist elektri- ja elektroonikaseadmetes.
Finnish	Suomi	FI	Seuraavaksi kuvatun vakuutuksen kohde direktiivin (EU) 2015/863 tiettyjen vaarallisten aineiden käytön rajoittamisesta sähkö- ja elektroniikkalaitteissa mukainen.
French	Français	FR	L'objet de la déclaration décrit ci-dessous est en conformité avec la Directive (UE) 2015/863 relative à la limitation de l'utilisation de certaines

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			substances dangereuses dans les équipements électriques et électroniques.
German	Deutsch	DE	Der unten beschriebene Gegenstand der Erklärung erfüllt die Richtlinie (EU) 2015/863 zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten.
Greek	Ελληνικά	EL	Το αντικείμενο της δήλωσης που περιγράφεται παρακάτω είναι σε συμμόρφωση με την οδηγία (ΕΕ) 2015/863, για τον περιορισμό της χρήσης ορισμένων επικίνδυνων ουσιών σε ηλεκτρικό και ηλεκτρονικό εξοπλισμό.
Hungarian	Magyar	HU	Az alább ismertetett nyilatkozat tárgya megfelel az (EU) 2015/863 számú, az egyes veszélyes anyagok elektromos és elektronikus berendezésekben való alkalmazásának korlátozásáról szóló irányelvének.
Italian	Italiano	IT	L'obiettivo della dichiarazione descritta di seguito è in conformità con la Direttiva (UE) 2015/863, sulla restrizione dell'uso di determinate sostanze pericolose nelle apparecchiature elettriche ed elettroniche.
Latvian	Latviešu	LV	Tālāk aprakstītais deklarācijas mērķis ir atbilstošs Direktīvai (ES) 2015/863 par dažu bīstamu vielu izmantošanas ierobežošanu elektriskās un elektroniskās iekārtās.
Lithuanian	Lietuvių	LT	Toliau aprašytas deklaracijos objektas atitinka direktyvą (ES) 2015/863 dėl tam tikrų pavojingų medžiagų naudojimo elektros ir elektroninėje įrangoje apribojimo.
Polish	Polski	PL	Przedmiot deklaracji opisanej poniżej jest zgodny z dyrektywą (UE) 2015/863 w sprawie ograniczenia stosowania niektórych niebezpiecznych substancji w sprzęcie elektrycznym i elektronicznym.
Portuguese	Português	PT	O objeto da declaração descrita abaixo está em conformidade com a Diretiva (EU) 2015/863 relativa à restrição do uso de determinadas substâncias perigosas em equipamentos eléctricos e electrónicos Texto relevante para efeitos do EEE.
Romanian	Română	RO	Obiectivul declarației descrise mai jos este în conformitate cu Directiva (UE) 2015/863 privind restricțiile de utilizare a anumitor substanțe periculoase în echipamentele electrice și electronice.
Slovak	Slovenčina	SK	Predmet tohto nižšie uvedeného vyhlásenia je v súlade so smernicou (EÚ) 2015/863 obmedzení používania určitých nebezpečných látok v elektrických a elektronických zariadeniach.

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Slovenian	Slovenščina	SI	Predmet spodaj opisane izjave je skladen z Direktivo (EU) 2015/863 omejevanju uporabe nekaterih nevarnih snovi v električni in elektronski opremi.
Spanish	Español	ES	El objeto de la declaración descrita a continuación es conforme a la Directiva (UE) 2015/863, sobre restricciones a la utilización de determinadas sustancias peligrosas en aparatos eléctricos y electrónicos.
Swedish	Svenska	SE	Föremål för de uppgifter som beskrivs nedan överensstämmer med direktiv (EU) 2015/863 om restriktionen av användningen av vissa farliga substanser i elektrisk och elektronisk utrustning.

Concerning Batteries and Waste Batteries Statement[30] European Language Translations:

Language[28]		Code	Concerning Batteries and Waste Batteries Statement
EN	Local		
Bulgarian	български език	BG	Предметът на декларацията, описан по-долу, съдържа батерия, която е в съответствие с Регламент (ЕС) 2023/1542.
Croatian	Hrvatski	HR	Predmet ove izjave sadrži bateriju koja je u skladu s Uredbom (EU) 2023/1542.
Czech	Český Jazyk	CZ	Níže popsaný předmět prohlášení obsahuje baterii, která je v souladu s nařízením (EU) 2023/1542.
Danish	Dansk	DK	Genstanden for erklæringen beskrevet nedenfor er et batteri, der er i overensstemmelse med forordning (EU) 2023/1542.
Dutch	Nederlands	NL	Het voorwerp van de hieronder beschreven verklaring bevat een batterij die voldoet aan Verordening (EU) 2023/1542.
Estonian	Eesti	EE	Allpool kirjeldatud deklareeritav toode sisaldab akut, mis vastab määrusele (EL) 2023/1542.
Finnish	Suomi	FI	Alla kuvatun ilmoituksen kohteena oleva laite sisältää pariston, joka on asetuksen (EU) 2023/1542 mukainen.
French	Français	FR	L'objet de la déclaration décrite ci-dessous contient une batterie conforme au règlement (UE) 2023/1542.
German	Deutsch	DE	Der nachstehend beschriebene Gegenstand der Erklärung enthält eine Batterie, die der Verordnung (EU) 2023/1542 entspricht.
Greek	Ελληνικά	EL	Το αντικείμενο της δήλωσης που περιγράφεται παρακάτω περιέχει μια μπαταρία που συμμορφώνεται με τον Κανονισμό (ΕΕ) 2023/1542.

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Hungarian	Magyar	HU	Az alább ismertetett nyilatkozat tárgya az (EU) 2023/1542 rendeletnek megfelelő akkumulátort vagy elemet tartalmaz.
Italian	Italiano	IT	L'oggetto della dichiarazione di cui sotto contiene una batteria conforme al Regolamento (UE) 2023/1542.
Latvian	Latviešu	LV	Tālāk aprakstītās deklarācijas priekšmets satur bateriju, kas atbilst Regulai (ES) 2023/1542.
Lithuanian	Lietuvių	LT	Toliau aprašytos deklaracijos objektas yra maitinimo elementas (akumuliatorius), atitinkantis Reglamentą (ES) 2023/1542.
Polish	Polski	PL	Przedmiot deklaracji opisany poniżej zawiera baterię zgodną z rozporządzeniem (UE) 2023/1542.
Portuguese	Português	PT	O objeto da declaração abaixo descrita contém uma bateria que está em conformidade com o Regulamento (UE) 2023/1542.
Romanian	Română	RO	Obiectul declarației descrise mai jos conține o baterie care este în conformitate cu Regulamentul (UE) 2023/1542.
Slovak	Slovenčina	SK	Nižšie opísaný predmet vyhlásenia obsahuje batériu, ktorá je v súlade s nariadením (EÚ) 2023/1542.
Slovenian	Slovenščina	SI	Predmet spodaj opisane izjave vsebuje baterijo, ki je skladna z Uredbo (EU) 2023/1542.
Spanish	Español	ES	El objeto de la declaración que se describe a continuación contiene una pila que cumple con lo estipulado en el Reglamento (UE) 2023/1542.
Swedish	Svenska	SE	Föremålet för deklarationen som beskrivs nedan innehåller ett batteri som överensstämmer med EU-förordning 2023/1542.

Appendices - European Language Term Translations:

Appendix no.	Language (EN)	Language (Local)	Country Code
Appendix 1	Bulgarian	български език	BG
Appendix 2	Croatian	Hrvatski	HR
Appendix 3	Czech	Český Jazyk	CZ
Appendix 4	Danish	Dansk	DK
Appendix 5	Dutch	Nederlands	NL
Appendix 6	Estonian	Eesti	EE
Appendix 7	Finnish	Suomi	FI
Appendix 8	French	Français	FR
Appendix 9	German	Deutsch	DE

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Appendix 10	Greek	Ελληνικά	GR
Appendix 11	Hungarian	Magyar	HU
Appendix 12	Italian	Italiano	IT
Appendix 13	Latvian	Latviešu	LV
Appendix 14	Lithuanian	Lietuvių	LT
Appendix 15	Polish	Polski	PL
Appendix 16	Portuguese	Português	PT
Appendix 17	Romanian	Română	RO
Appendix 18	Slovak	Slovenčina	SK
Appendix 19	Slovenian	Slovenščina	SL
Appendix 20	Spanish	Español	ES
Appendix 21	Swedish	Svenska	SE

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Appendix 1			
Language (EN)	Bulgarian (BG)	**Language (Local)**	български език

No.	Translated Term
1	ЕВРОПЕЙСКА ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ
2	Декларацията потвърждава, че посоченият по-долу продукт съответства на: Регламент 2017/745, [въведете друго уместно европейско законодателство, според приложимото] и се издава единствено на отговорност на име на законния производител
3	Име на производител
4	Бизнес адрес
5	Единен регистрационен номер (EPH)
6	Упълномощен представител за Европа
7	Бизнес адрес
8	Име на продукт: (вижте приложения опис за продуктови кодове/каталожни номера)
9	Предназначение: Вижте таблицата за други езици
10	Процедура за оценяване на съответствието (Приложение)
11	Име на нотифициран орган
12	Номер на нотифициран орган
13	Сертификат(и) за проверка
14	Подписан от името на име на законния производител
15	Подпис
16	Име
17	Длъжност
18	Дата
19	Местоположение
20	Справка за декларация за съответствие
21	Продуктов опис
22	Продуктов код / Каталожен номер
23	Описание на продукта или Вариант на продукта
24	Класификация в зависимост от риска
25	Основен уникален идентификатор на изделията - идентификатор на изделията
26	Стандарти / Обща(и) спецификация(и)
27	Предназначение: Преводи на европейски езици
28	Език
29	Декларация за електрическо и електронно оборудване (EEO)
30	Декларация относно батериите и отпадните батерии

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Appendix 2			
Language (EN)	Croatian (HR)	**Language (Local)**	Hrvatski

No.	Translated Term
1	EUROPSKA IZJAVA O SUKLADNOSTI
2	Izjavom se potvrđuje da je niže navedeni proizvod u skladu s: Uredbama 2017/745, [unesite ostale mjerodavne Europske zakone, kako je primjenjivo]. Odgovornost za njeno izdavanje snosi isključivo [naziv proizvođača]
3	Naziv proizvođača
4	Adresa proizvođača
5	Jedinstveni registracijski broj (SRN)
6	Ovlašteni zastupnik za Europu
7	Adresa ovlaštenog zastupnika
8	Naziv proizvoda: (šifre proizvoda/kataloške brojeve potražite u priloženom dodatku)
9	Namjena: Vidi tablicu za ostale jezike
10	Postupak procjenjivanja sukladnosti (Prilog)
11	Naziv prijavljenog tijela
12	Broj prijavljenog tijela
13	Potvrda (potvrde) o provjeri
14	Potpisao/-la u ime [naziv proizvođača]
15	Potpis
16	Ime I prezime
17	Funkcija
18	Datum
19	Mjesto
20	Oznaka izjave o sukladnosti
21	Dodatak za proizvod
22	Šifra proizvoda / kataloški broj
23	Opis proizvoda ili inačica proizvoda
24	Klasa rizika
25	Osnovna jedinstvena identifikacija proizvoda-identifikator proizvoda (UDI-DI)
26	Norme / Uobičajena specifikacija (Uobičajene specifikacije)
27	Namjena: prijevodi na europske jezike
28	Jezik
29	Izjava o električnoj i elektroničkoj opremi (EEO)
30	Izjava o baterijama i otpadnim baterijama

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Appendix 3			
Language (EN)	Czech (CZ)	**Language (Local)**	Český Jazyk

No.	Translated Term
1	EVROPSKÉ PROHLÁŠENÍ O SHODĚ
2	Prohlášení potvrzuje, že níže uvedený výrobek splňuje nařízení 2017/745 [případně doplňte další příslušné evropské právní předpisy], a je vydáno na výhradní zodpovědnost [oficiální název výrobce]
3	Název výrobce
4	Adresa místa podnikání
5	Jediné registrační číslo
6	Oprávněný zástupce pro Evropu
7	Adresa místa podnikání
8	Název výrobku: (kód výrobku / katalogové číslo viz přiložený soupis)
9	Určené použití: Viz tabulka pro další jazyky
10	Postup posuzování shody (příloha)
11	Název oznámeného subjektu
12	Číslo oznámeného subjektu
13	Osvědčení o ověření
14	Podepsáno jménem [oficiální název výrobce]
15	Podpis
16	Jméno
17	Pozice
18	Datum
19	Místo
20	Prohlášení o shodě – reference
21	Soupis výrobků
22	Kód výrobku / katalogové číslo
23	Popis výrobku nebo varianta výrobku
24	Klasifikace rizik
25	Základní UDI-DI
26	Normy / společné specifikace
27	Zamýšlené použití: překlad do evropských jazyků
28	Jazyk
29	Prohlášení o elektrických a elektronických zařízeních (EEZ)
30	Prohlášení o bateriích a odpadních bateriích

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Appendix 4			
Language (EN)	Danish (DK)	**Language (Local)**	Dansk

No.	Translated Term
1	EUROPÆISK OVERENSSTEMMELSESERKLÆRING
2	Erklæringen bekræfter, at produkterne angivet herunder overholder: Forordning 2017/745, [indsæt anden gældende europæisk lovgivning hvis relevant] og er udstedt med eneansvar for [Juridisk fabrikantnavn]
3	Fabrikantens navn
4	Virksomhedsadresse
5	Individuelt registreringsnummer (Single Registration Number, SRN)
6	Autoriseret europæisk repræsentant
7	Virksomhedsadresse
8	Produktnavn: (se vedlagte bilag for produktkoder/katalognumre)
9	Tilsigtet brug: Se tabel for andre sprog
10	Procedure for overensstemmelsesvurdering (bilag)
11	Bemyndiget organ, navn
12	Bemyndiget organ, nummer
13	Verifikationscertifikat(er)
14	Underskrevet på vegne af [Juridisk fabrikantnavn]
15	Underskrift
16	Navn
17	Position
18	Dato
19	Placering
20	Overensstemmelseserklæring, reference
21	Produktbilag
22	Produktkode/katalognummer
23	Produktbeskrivelse eller produktvariant
24	Risikoklasse
25	Grundlæggende UDI-DI
26	Standarder/almindelig(e) specifikation(er)
27	Tilsigtet brug: Oversættelser på europæiske sprog
28	Sprog
29	Erklæring vedrørende elektrisk og elektronisk udstyr (EEE)
30	Erklæring vedrørende batterier og udtjente batterier

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Appendix 5			
Language (EN)	Dutch (NL)	**Language (Local)**	Nederlands

No.	Translated Term
1	EUROPESE CONFORMITEITSVERKLARING
2	Deze verklaring bevestigt dat het hieronder vermelde product voldoet aan: Verordening 2017/745, [andere relevante Europese wetgeving invoegen indien van toepassing] en wordt uitgegeven onder de uitsluitende verantwoordelijkheid van [wettige naam van fabrikant]
3	Naam van de fabrikant
4	Bedrijfsadres
5	SRN (single registration number: uniek registratienummer)
6	Geautoriseerde vertegenwoordiger voor Europa
7	Bedrijfsadres
8	Productnaam: (zie bijgevoegd bijlage voor productcodes/catalogusnummers)
9	Beoogd gebruik: Zie de tabel voor andere Europese talen
10	Conformiteitsbeoordelingsprocedure (bijlage)
11	Naam van aangemelde instantie
12	Nummer van aangemelde instantie
13	Verificatiecertificaat/-certificaten
14	Ondertekend namens [naam van de fabrikant]
15	Handtekening
16	Naam
17	Functie
18	Datum
19	Plaats
20	Referentie conformiteitsverklaring
21	Productschema
22	Productcode/catalogusnummer
23	Productbeschrijving of productvariant
24	Risicoclassificatie
25	Basis UDI-DI
26	Standaarden/Algemene specificatie(s)
27	Beoogd gebruik: vertalingen in Europese talen
28	Taal
29	Verklaring elektrische en elektronische apparatuur (EEA)
30	Verklaring inzake batterijen en afgedankte batterijen

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Appendix 6			
Language (EN)	Estonian (EE)	**Language (Local)**	Eesti

No.	Translated Term
1	EUROOPA VASTAVUSDEKLARATSIOON
2	Selle deklaratsiooniga kinnitame allpool loetletud toote vastavust: määrusele 2017/745 [sisestage muu Euroopa õigusakt, kui on kohaldatav] ning see väljastatakse [seadusliku tootja nimi] ainuvastutusel
3	Tootja nimi
4	Registreeritud aadress
5	Unikaalne registreerimisnumber (SRN)
6	Volitatud esindaja Euroopas
7	Registreeritud aadress
8	Toote nimetus: (tootekoode/kataloginumbreid vt lisatud tabelist)
9	Ettenähtud kasutusotstarve: Teisi keeli vt tabelist
10	Vastavushindamise protseduur (lisa)
11	Teavitatud asutuse nimetus
12	Teavitatud asutuse number
13	Kinnitussertifikaat/-sertifikaadid
14	Allkirjastanud [seadusliku tootja nimi]
15	Allkiri
16	Nimi
17	Ametikoht
18	Kuupäev
19	Asukoht
20	Vastavusdeklaratsiooni viide
21	Toote tabel
22	Tootekood/kataloginumber
23	Toote kirjeldus või toote variant
24	Riski klassifikatsioon
25	Põhiline UDI-DI
26	Standardid / ühtsed tehnilised tingimused
27	Ettenähtud kasutusotstarve Tõlked Euroopa keeltesse
28	Keel
29	Elektri- ja elektroonikaseadmete (EEE) avaldus
30	Avaldus, mis käsitleb akusid ja patareisid ning patarei- ja akujäätmeid

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Appendix 7			
Language (EN)	Finnish (FI)	**Language (Local)**	Suomi

No.	Translated Term
1	EUROOPPALAINEN VAATIMUSTENMUKAISUUSVAKUUTUS
2	Vakuutuksella vahvistetaan, että jäljempänä mainittu tuote täyttää: Asetuksen 2017/745, [tähän tulee lisätä muu asiaan liittyvä eurooppalainen lainsäädäntö sikäli kuin sitä on] mukaiset vaatimukset, ja annetusta vakuutuksesta vastuussa on yksinomaan [laillisen valmistajan nimi]
3	Valmistajan nimi
4	Toimipaikan osoite
5	Rekisterinumero (SRN)
6	Eurooppalainen valtuutettu edustaja
7	Toimipaikan osoite
8	Tuotteen nimi: (ks. liitteestä tuotekoodit/luettelonumerot)
9	Käyttötarkoitus: Taulukossa esitetään muut kieliversiot
10	Vaatimustenmukaisuuden arviointimenettely (Liite)
11	Ilmoitetun laitoksen nimi
12	Ilmoitetun laitoksen numero
13	Tarkastustodistus (-todistukset)
14	Allekirjoitettu puolesta [laillisen valmistajan nimi]
15	Allekirjoitus
16	Nimi
17	Asema
18	Päiväys
19	Paikka
20	Vaatimustenmukaisuusvakuutuksen viite
21	Tuoteluettelo
22	Tuotekoodi / Luettelonumero
23	Tuotekuvaus tai tuotevariantti
24	Riskiluokitus
25	Perus-UDI-DI-tunniste
26	Standardit / Yhteinen eritelmä (tai monikossa)
27	Käyttötarkoitus Käännökset Euroopan kielillä
28	Kieli
29	Ilmoitus sähkö- ja elektroniikkalaitteesta (EEE)
30	Lausunto akuista ja paristoista ja jäteakuista ja -paristoista

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Appendix 8			
Language (EN)	French (FR)	**Language (Local)**	Français

No.	Translated Term
1	DÉCLARATION DE CONFORMITÉ EU
2	La déclaration confirme que le produit repris ci-dessous est conforme au : Règlement (UE) 2017/745 [insérer au besoin toute autre législation européenne pertinente] et est publiée sous la seule responsabilité de Nom du fabricant légal
3	Nom du fabricant
4	Adresse professionnelle
5	Numéro d'enregistrement unique
6	Mandataire établi dans l'UE
7	Adresse professionnelle
8	Nom du produit : (voir l'annexe jointe pour les codes de produit/références catalogue)
9	Usage prévu : Voir le tableau pour les autres langues
10	Procédure d'évaluation de la conformité (Annexe)
11	Nom de l'organisme notifié
12	N° de l'organisme notifié
13	Certificat(s) de vérification
14	Signé au nom de Nom du fabricant légal
15	Signature
16	Nom
17	Fonction du signataire
18	Date
19	Adresse
20	Référence de la déclaration de conformité
21	Information produit
22	Code du produit / Référence catalogue du produit
23	Description du produit ou variante du produit
24	Classe de risque
25	Identifiant « dispositif » IUD (IUD-ID)
26	Normes / Spécification(s) commune(s)
27	Usage prévu : traduction dans les langues européennes
28	Langue
29	Déclaration sur les équipements électriques et électroniques (EEE)
30	Déclaration relative aux batteries et aux déchets de batteries

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Appendix 9			
Language (EN)	German (DE)	**Language (Local)**	Deutsch

No.	Translated Term
1	EUROPÄISCHE KONFORMITÄTSERKLÄRUNG
2	Mit dieser Erklärung wird bestätigt, dass das unten aufgeführte Produkt den folgenden Anforderungen entspricht: Verordnungen 2017/745, [ggf. andere einschlägige europäische Rechtsvorschriften einfügen]. Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt [Name des Herstellers]
3	Name des Herstellers
4	Geschäftsadresse
5	Einmalige Registrierungsnummer (SRN)
6	Europäischer Bevollmächtigter
7	Geschäftsadresse
8	Produktname: (Produktcodes/Katalognummern siehe beigefügtes Verzeichnis)
9	Verwendungszweck: Andere Sprachen siehe Tabelle
10	Konformitätsbewertungsverfahren (Anhang)
11	Name der benannten Stelle
12	Nummer der benannten Stelle
13	Prüfzertifikat(e)
14	Unterzeichnet im Auftrag von Name des Herstellers
15	Unterschrift
16	Name
17	Position
18	Datum
19	Standort
20	Konformitätserklärung – Referenz
21	Produktverzeichnis
22	Produktcode/Katalognummer
23	Produktbeschreibung oder Produktvariante
24	Risikoklassifizierung
25	Basis-UDI-DI
26	Normen/Gemeinsame Spezifikation(en)
27	Verwendungszweck: Übersetzung in europäische Sprachen
28	Sprache
29	Hinweis für Elektro- und Elektronikgeräte (EEE)
30	Erklärung über Batterien und Altbatterien

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Appendix 10			
Language (EN)	Greek (GR)	**Language (Local)**	Ελληνικά

No.	Translated Term
1	ΕΥΡΩΠΑΪΚΗ ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ
2	Η δήλωση επιβεβαιώνει ότι το προϊόν που αναφέρεται παρακάτω πληροί: τους κανονισμούς 2017/745, [συμπληρώστε άλλη σχετική ευρωπαϊκή νομοθεσία ανάλογα με την περίπτωση] και εκδίδεται υπό την αποκλειστική ευθύνη του [επωνυμία νόμιμου κατασκευαστή]
3	Επωνυμία κατασκευαστή
4	Διεύθυνση επιχείρησης
5	Ενιαίος αριθμός καταχώρισης (SRN)
6	Εξουσιοδοτημένος αντιπρόσωπος στην Ευρώπη
7	Διεύθυνση επιχείρησης
8	Ονομασία προϊόντος: (βλ. συνημμένο παράρτημα κωδικών προϊόντων/αριθμών καταλόγου)
9	Προβλεπόμενη χρήση: βλ. πίνακα για άλλες γλώσσες
10	Διαδικασία εκτίμησης της συμμόρφωσης (παράρτημα)
11	Επωνυμία κοινοποιημένου οργανισμού
12	Αριθμός κοινοποιημένου οργανισμού
13	Πιστοποιητικό(ά) επαλήθευσης
14	Υπογραφή εξ ονόματος του [επωνυμία νόμιμου κατασκευαστή]
15	Υπογραφή
16	Ονοματεπώνυμο
17	Τίτλος
18	Ημερομηνία
19	Τοποθεσία
20	Αναφορά δήλωσης συμμόρφωσης
21	Παράρτημα προϊόντων
22	Κωδικός προϊόντος/Αριθμός καταλόγου
23	Περιγραφή προϊόντος ή παραλλαγή προϊόντος
24	Ταξινόμηση κινδύνου
25	Βασικό UDI-DI
26	Πρότυπα/Κοινή(ές) προδιαγραφή(ές)
27	Προβλεπόμενη χρήση: μεταφράσεις σε ευρωπαϊκές γλώσσες
28	Γλώσσα
29	Δήλωση συμμόρφωσης ηλεκτρικού και ηλεκτρονικού εξοπλισμού (ΗΗΕ)
30	Δήλωση σχετικά με τις μπαταρίες και τα απόβλητα μπαταριών

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Appendix 11			
Language (EN)	Hungarian (HU)	**Language (Local)**	Magyar

No.	Translated Term
1	EURÓPAI MEGFELELŐSÉGI NYILATKOZAT
2	A nyilatkozat megerősíti, hogy az alább felsorolt termék megfelel a következőknek: A 2017/745 rendeletek, [értelemszerűen illessze be ide az egyéb fontos európai jogszabályokat], és kiadása a [gyártó hivatalos neve] kizárólagos felelősségére történik
3	A gyártó neve
4	Székhelye
5	Egyedi nyilvántartási szám (SRN)
6	Meghatalmazott európai képviselő
7	Székhelye
8	A termék neve: (lásd a mellékelt listát a termékkódokat/katalógusszámokat illetően)
9	Rendeltetésszerű használat: Az egyéb nyelveket lásd a táblázatban
10	Megfelelőségértékelési eljárás (melléklet)
11	Kijelölt szervezet neve
12	Kijelölt szervezet száma
13	Hitelesítési tanúsítvány(ok)
14	Aláírva a [gyártó hivatalos neve] nevében
15	Aláírás
16	Név
17	Beosztás
18	Dátum
19	Hely
20	A megfelelőségi nyilatkozat hivatkozása
21	Terméklista
22	Termékkód/katalógusszám
23	A termék leírása vagy termékváltozat
24	Kockázatbesorolás
25	Alap UDI-DI
26	Szabványok / általános specifikáció(k)
27	A rendeltetésszerű használat európai nyelvre történt fordítása
28	Nyelv
29	Elektromos és elektronikus berendezésekre vonatkozó nyilatkozat (EEE)
30	Az elemekről, illetve akkumulátorokról és a hulladékelemekről, illetve -akkumulátorokról szóló nyilatkozat

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Appendix 12			
Language (EN)	Italian (IT)	**Language (Local)**	Italiano

No.	Translated Term
1	DICHIARAZIONE DI CONFORMITÀ EUROPEA
2	La dichiarazione conferma che il prodotto menzionato di seguito è conforme a: Regolamento 2017/745, [inserire altre normative europee pertinenti per quanto applicabile], ed è rilasciata sotto l'esclusiva responsabilità del fabbricante legale
3	Nome del fabbricante
4	Indirizzo aziendale
5	Numero di registrazione unico (Single Registration Number, SRN)
6	Rappresentante europeo autorizzato
7	Indirizzo aziendale
8	Nome del prodotto: (vedere il prospetto allegato per i codici di prodotto/numeri di catalogo)
9	Uso previsto: vedere la tabella per le altre lingue
10	Procedura di valutazione di conformità (Allegato)
11	Nome dell'organismo notificato
12	Numero dell'organismo notificato
13	Certificazione/i di verifica
14	Firmato in nome e per conto di (nome del fabbricante legale)
15	Firma
16	Nome
17	Posizione professionale
18	Data
19	Sede
20	Riferimento per la Dichiarazione di conformità
21	Prospetto prodotti
22	Codice prodotto/Numero di catalogo
23	Descrizione del prodotto o variante di prodotto
24	Classificazione del rischio
25	Codice UDI-DI
26	Norme/Specifiche comuni
27	Uso previsto: traduzioni nelle lingue europee
28	Lingua
29	Dichiarazione relativa alle apparecchiature elettriche ed elettroniche (AEE)
30	Dichiarazione relativa alle batterie e ai rifiuti delle batterie

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Appendix 13			
Language (EN)	Latvian (LV)	**Language (Local)**	Latviešu

No.	Translated Term
1	EIROPAS ATBILSTĪBAS DEKLARĀCIJA
2	Deklarācija apliecina, ka tālāk norādītais produkts atbilst: Regulām 2017/745, [ievietojiet citus atbilstošus Eiropas tiesību aktus, kā nepieciešams], un tā ir izsniegta tikai uz [ražotāja juridiskais nosaukums] atbildību
3	Ražotāja nosaukums
4	Uzņēmuma adrese
5	Vienotais reģistrācijas numurs (VRN)
6	Pilnvarotais pārstāvis Eiropā
7	Uzņēmuma adrese
8	Produkta nosaukums: (produkta kodus/kataloga numurus skatīt pievienotajā pielikumā)
9	Paredzētā lietošana: informāciju par citām valodām skatīt tabulā
10	Atbilstības novērtēšanas procedūra (Pielikums)
11	Paziņotās struktūras nosaukums
12	Paziņotās struktūras numurs
13	Pārbaudes sertifikāts(-i)
14	Parakstīts [ražotāja juridiskais nosaukums] vārdā
15	Paraksts
16	Vārds, uzvārds
17	Amats
18	Datums
19	Vieta
20	Atbilstības deklarācijas atsauce
21	Produkta pielikums
22	Produkta kods/kataloga numurs
23	Produkta apraksts vai produkta variants
24	Riska klasifikācija
25	Pamata UDI-DI
26	Standarti/vispārīgā(-s) specifikācija(-s)
27	Paredzētā lietošana: tulkojumi Eiropas valodās
28	Valoda
29	Paziņojums par elektriskajām un elektroniskajām iekārtām (EEI)
30	Paziņojums par baterijām un bateriju atkritumiem

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Appendix 14			
Language (EN)	Lithuanian (LT)	**Language (Local)**	Lietuvių

No.	Translated Term
1	Europos Atitikties Deklaracija
2	Delaracija patvirtina kad toliau išvardyti produktai atitinka: Reglamentą 2017/745, [įterpti kitus taikytinus Europos teisės aktus] ir už jo išdavimą yra visiškai atsakingas [legalus gamintojo vardas].
3	Gamintojo pavadinimas
4	Verslo adresas
5	Bendras Registracijos Numeris (BRN)
6	Europos įgaliotasis atstovas
7	Verslo adresas
8	Produkto vardas: (produktų kodus / katalogo numerius žiūrėkite priede)
9	Paskirtis: kitomis kalbomis žiūrėkite lentelę
10	Atitikties deklaracija (priedas)
11	Notifikuotosios įstaigos pavadinimas
12	Notifikuotosios įstaigos numeris
13	Patvirtinimo sertifikatas (-ai)
14	Pasirašyta (legalaus gamintojo vardas) vardu
15	Parašas
16	Vardas
17	Pareigos
18	Data
19	Vieta
20	Atitikties Deklaracijos Nuoroda
21	Produktų sąrašas
22	Produkto Kodas/ Katalogo numeris
23	Produkto Apibūdinimas arba Produkto Variantas
24	Rizikos Klasifikacija
25	Pagrindinis UDI
26	Standartai / Bendroji specifikacija (-os)
27	Numatomi vartoti Europos šalių kalbų vertimai
28	Kalba
29	Elektros ir elektroninės įrangos (EEĮ) pareiškimas
30	Pareiškimas dėl maitinimo elementų (akumuliatorių) ir jų atliekų

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Appendix 15			
Language (EN)	Polish (PL)	**Language (Local)**	Polski

No.	Translated Term
1	EUROPEJSKA DEKLARACJA ZGODNOŚCI
2	Deklaracja potwierdza, że wymieniony poniżej produkt spełnia wymagania: Rozporządzenia 2017/745 [w razie potrzeby wstawić inne stosowne przepisy europejskie] i jest wydawana na wyłączną odpowiedzialność Nazwa producenta
3	Nazwa producenta
4	Adres firmy
5	Niepowtarzalny numer rejestracyjny (SRN)
6	Upoważniony przedstawiciel w Unii Europejskiej
7	Adres firmy
8	Nazwa produktu: (kody produktów / numery katalogowe zawiera załączony wykaz)
9	Przewidziane używanie : Tekst w innych językach znajduje się w tabeli
10	Procedura oceny zgodności (załącznik)
11	Nazwa jednostki notyfikowanej
12	Numer jednostki notyfikowanej
13	Certyfikaty weryfikacji
14	Podpisano w imieniu Nazwa producenta
15	Podpis
16	Imię i nazwisko
17	Stanowisko
18	Data
19	Miejsce
20	Numer referencyjny deklaracji zgodności
21	Wykaz produktów
22	Kod produktu / numer katalogowy
23	Opis produktu lub wariant produktu
24	Klasyfikacja ryzyka
25	Kod Basic UDI-DI
26	Normy / wspólne specyfikacje
27	Tłumaczenia tekstu dotyczącego przeznaczenia produktu na języki europejskie
28	Język
29	Oświadczenie dotyczące sprzętu elektrycznego i elektronicznego (EEE)
30	Oświadczenie w sprawie baterii i zużytych baterii

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Appendix 16			
Language (EN)	Portuguese (PT)	**Language (Local)**	Português

No.	Translated Term
1	DECLARAÇÃO DE CONFORMIDADE EUROPEIA
2	A declaração confirma que os produtos listados abaixo cumprem: Regulamentação 2017/745, [inserir outra legislação europeia relevante, conforme aplicável] e é emitida sob a responsabilidade única do [Nome legal do fabricante]
3	Nome do fabricante
4	Endereço da empresa
5	Número único de registo (NUR)
6	Representante Europeu Autorizado
7	Endereço da empresa
8	Nome do produto: (consulte o anexo quanto a códigos de produtos/números de catálogo)
9	Finalidade: Consulte a tabela para outros idiomas
10	Procedimento de avaliação de conformidade (Anexo)
11	Nome do organismo notificado
12	Número do organismo notificado
13	Certificado(s) de verificação
14	Assinado em nome de [Nome legal do fabricante]
15	Assinatura
16	Nome
17	Cargo
18	Data
19	Localização
20	Referência de Declaração de conformidade
21	Anexo do produto
22	Código de produto / Número de catálogo
23	Descrição do produto ou variante do produto
24	Classificação de risco
25	UDI-DI básico
26	Normas / Especificação(ões) comum(ns)
27	Traduções da Finalidade para idiomas europeus
28	Idioma
29	Declaração sobre Equipamentos Elétricos e Eletrónicos (EEE)
30	Declaração relativa às baterias e respetivos resíduos

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Appendix 17			
Language (EN)	Romanian (RO)	**Language (Local)**	Română

No.	Translated Term
1	DECLARAȚIE DE CONFORMITATE EUROPEANĂ
2	Declarația confirmă faptul că produsul specificat mai jos respectă: Regulamentul 2017/745, [introduceți ale acte legislative europene relevante, după caz] și este emis pe propria răspundere a Denumirea juridică a producătorului
3	Denumirea producătorului
4	Sediul social
5	Număr unic de înregistrare (CUI)
6	Reprezentant european autorizat
7	Sediul social
8	Denumirea produsului: (consultați anexa atașată pentru codurile de produs/numerele de catalog)
9	Utilizare preconizată: consultați tabelul pentru alte limbi
10	Procedura de evaluare a conformității (Anexă)
11	Denumirea organismului notificat
12	Numărul organismului notificat
13	Certificat(e) de verificare
14	Semnat în numele Denumirea juridică a producătorului
15	Semnătură
16	Nume
17	Funcție
18	Dată
19	Locatie
20	Referință pentru declarația de conformitate
21	Anexa produsului
22	Cod produs / Număr de catalog
23	Descrierea produsului sau varianta produsului
24	Clasificarea riscurilor
25	UDI-DI (identificator unic de dispozitiv) de bază
26	Standarde / Specificație(i) comună(e)
27	Utilizare preconizată: traduceri în limbile europene
28	Limbă
29	Declarație privind echipamentele electrice și electronice (EEE)
30	Declarație privind bateriile și deșeurile de baterii

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Appendix 18			
Language (EN)	Slovak (SK)	**Language (Local)**	Slovenčina

No.	Translated Term
1	VYHLÁSENIE O ZHODE EÚ
2	Vyhlásenie potvrdzuje, že nižšie uvedený produkt spĺňa: nariadenia 2017/745, [vložiť ďalšie príslušné právne predpisy EÚ] a vydáva sa s výhradnou zodpovednosťou výrobcu s registrovaným názvom
3	Názov výrobcu
4	Sídlo spoločnosti
5	Jediné registračné číslo (SRN)
6	Oprávnený zástupca pre EÚ
7	Sídlo spoločnosti
8	Názov produktu: (pozri priložený dodatok s kódmi výrobkov/katalógovými číslami)
9	Plánované použitie: Ďalšie jazyky nájdete v tabuľke
10	Postup posudzovania zhody (príloha)
11	Názov notifikovaného orgánu
12	Číslo notifikovaného orgánu
13	Overovacie certifikáty
14	Podpísaný v mene výrobcu s registrovaným názvom
15	Podpis
16	Meno
17	Pozícia
18	Dátum
19	Miesto
20	Odkaz na vyhlásenie o zhode
21	Tabuľka výrobkov
22	Kód výrobku / katalógové číslo
23	Popis produktu alebo variant produktu
24	Klasifikácia rizika
25	Základný identifikátor UDI-DI
26	Normy / spoločné špecifikácie
27	Plánované použitie prekladov z jazykov EÚ
28	Jazyk
29	Vyhlásenie o elektrických a elektronických zariadeniach (EEE)
30	Vyhlásenie o batériách a odpadových batériách

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Appendix 19			
Language (EN)	Slovenian (SI)	**Language (Local)**	Slovenščina

No.	Translated Term
1	EVROPSKA IZJAVA O SKLADNOSTI
2	Izjava potrjuje, da spodaj navedeni izdelek ustreza: Uredbi 2017/745 [vstavite drugo zadevno evropsko zakonodajo, kakor je primerno], in je izdana na lastno odgovornost [Ime zakonitega proizvajalca]
3	Ime proizvajalca
4	Poslovni naslov
5	Enotna registrska številka (SRN)
6	Pooblaščeni zastopnik za Evropo
7	Poslovni naslov
8	Ime izdelka: (glejte priložen dodatek s kodami/katalоškimi številkami izdelkov)
9	Predvidena uporaba: Za druge jezike glejte preglednico
10	Postopek ugotavljanja skladnosti (Priloga)
11	Ime priglašenega organa
12	Številka priglašenega organa
13	Potrdilo(-a) o verifikaciji
14	Podpisano v imenu Ime zakonitega proizvajalca
15	Podpis
16	Ime
17	Delovno mesto
18	Datum
19	Kraj
20	Referenca Izjave o skladnosti
21	Dodatek z izdelki
22	Koda/kataloška številka izdelka
23	Opis izdelka ali različica izdelka
24	Razvrščanje v razred tveganja
25	Osnovni UDI-DI
26	Standardi/splošne specifikacije
27	Prevodi predvidene uporabe v evropske jezike
28	Jezik
29	Izjava o električni in elektronski opremi (EEO)
30	Izjava o baterijah in odpadnih baterijah

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Appendix 20			
Language (EN)	Spanish (ES)	**Language (Local)**	Español

No.	Translated Term
1	DECLARACIÓN UE DE CONFORMIDAD
2	Esta declaración confirma que el producto indicado a continuación cumple con lo estipulado en el Reglamento (UE) 2017/745, [incluir otras normativas europeas pertinentes que sean de aplicación] y se publica bajo la exclusiva responsabilidad de [Nombre legal del fabricante]
3	Nombre del fabricante
4	Domicilio social
5	Número de registro único (SRN)
6	Representante autorizado en Europa
7	Domicilio social
8	Nombre del producto: (véase el apéndice para comprobar los códigos/números de catálogo de los productos)
9	Uso previsto: véase la tabla para consultar otros idiomas
10	Procedimiento de evaluación de la conformidad (anexo)
11	Nombre del organismo notificado
12	Número del organismo notificado
13	Certificados de verificación
14	Firmado en nombre de [Nombre legal del fabricante]
15	Firma
16	Nombre
17	Puesto
18	Fecha
19	Ubicación
20	Referencia de la declaración de conformidad
21	Apéndice del producto
22	Código/número de catálogo del producto
23	Descripción o variante del producto
24	Clasificación del riesgo
25	UDI-DI básica
26	Normas/especificaciones comunes
27	Uso previsto: traducciones a idiomas europeos
28	Idioma
29	Declaración sobre aparatos eléctricos y electrónicos (AEE)
30	Declaración relativa a las pilas y baterías y sus residuos

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Appendix 21			
Language (EN)	Swedish (SE)	**Language (Local)**	Svenska

No.	Translated Term
1	EUROPEISK FÖRSÄKRAN OM ÖVERENSSTÄMMELSE
2	Denna försäkran bekräftar att produkten som anges nedan uppfyller: kraven i förordning 2017/745, [infoga annan relevant Europeisk lagstiftning om tillämpligt] och utfärdas på eget ansvar av [tillverkarens namn]
3	Tillverkarens namn
4	Företagsadress
5	Eudamed-registreringsnummer (SRN)
6	Auktoriserad representant i Europa
7	Företagsadress
8	Produktnamn: (se den bifogade översikten för produktkoder/katalognummer)
9	Avsedd användning: Se tabellen för andra språk
10	Procedur för bedömning av överensstämmelse (bilaga)
11	Anmälda organets namn
12	Anmälda organets identifikationsnummer
13	Verifieringscertifikat
14	Undertecknat på [tillverkarens namn]:s vägnar
15	Underskrift
16	Namn
17	Befattning
18	Datum
19	Placering
20	Referens för försäkran om överensstämmelse
21	Produktöversikt
22	Produktkod/katalognummer
23	Produktbeskrivning eller produktvariant
24	Riskklassificering
25	Grundläggande UDI-DI
26	Standarder/gemensam(ma) specifikation(er)
27	Avsedd användning av översättningar till europeiska språk
28	Språk
29	Uttalande om elektrisk och elektronisk utrustning (EEE)
30	Meddelande om batterier och förbrukade batterier

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