

Legally Strong Product Liability Waiver Framework for WellnessBox Electrotherapy Device

This report is legal information and drafting support (not legal advice). Because no jurisdiction is specified, the analysis is U.S.-wide and uses conservative assumptions, optional clause “risk tiers,” and placeholders you can lock down once you provide governing-law and sales-footprint details. ¹

Goals, assumptions, and missing inputs to finalize

Goal. Create a product-liability waiver/release package that (a) maximizes enforceability in typical consumer ecommerce transactions, (b) is tailored to electrotherapy risks, (c) coordinates with warranty law, consumer protection, and device-regulatory constraints, and (d) can be shown to each legally relevant person (purchaser and end user) with auditable assent and version control. ²

Key working assumptions (to replace with facts).

WellnessBox is marketed as an electro-therapy device for “muscle comfort and recovery routines,” sold online at getwellnessbox.com, with wellness-style “not medical advice / not FDA-evaluated / not intended to diagnose, treat, cure, or prevent any disease” language. ³

Missing inputs (please answer so the draft can be “jurisdiction-locked” and operationalized).

Needed input	Why it matters for enforceability and compliance
Chosen governing law + forum (e.g., Illinois law + Cook County, IL)	State law drives waiver public-policy limits, warranty anti-disclaimer statutes, and unconscionability tests. ⁴
Primary sales states (top 5–10 by shipments)	Lets you tailor disclosures and decide whether to exclude or special-handle “strict” states (e.g., anti-disclaimer warranty statutes). ⁵
Age restrictions (18+ only? allowed supervised teen use?)	Minors’ contracts are commonly voidable; many states restrict parents’ ability to waive minors’ future injury claims. Your safest engineering choice is “18+ to purchase; 18+ to use unless supervised” with activation gating. ⁶
Warranty terms / return policy (existence and duration of written warranty; any service contract)	A “written warranty” can trigger Magnuson–Moss limits on implied-warranty disclaimers; timing and pre-sale availability rules also matter online. ⁷
Whether you claim “pain relief” or other medical indications anywhere	Claims can shift the product into regulated device categories (e.g., TENS for pain relief) and raise labeling and regulatory obligations. ⁸

Needed input	Why it matters for enforceability and compliance
Insurance (GL/product liability + limits; any indemnity from suppliers)	Determines whether it is rational to offer higher consumer-friendly caps or to keep aggressive limitations; also informs indemnity drafting. (No single statute citation; this is risk allocation practice.)
Entity / signer details for the UNA (authorized signatories; “doing business as” name; service-of-process address)	Ensures the contracting party is clearly identified and helps avoid capacity/authority disputes in enforcement. ⁹

Product and regulatory context that shapes waiver scope and wording

What WellnessBox appears to be from public-facing materials

Public materials describe WellnessBox as a consumer electro-therapy device for muscle comfort/recovery, sold online, and include wellness-style medical disclaimers. Those statements help support a “general wellness” positioning, but they do not alone determine legal classification; **intended use** is inferred from “labeling,” advertising, and representations. ¹⁰

Why electrical stimulation elevates both safety and regulatory scrutiny

The “[entity]”[“organization”,“U.S. Food and Drug Administration”,“us medical products regulator”] has repeatedly treated certain “interventions or technologies” as potentially **not low risk** for general wellness policy purposes. The updated FDA “General Wellness: Policy for Low Risk Devices” guidance (Jan 2026) gives an explicit example: **a neurostimulation product claimed to improve memory is not low risk because of risks from electrical stimulation.** ¹¹

This matters for waiver drafting in two ways:

First, it supports **plain-English warnings** about electrical-stimulation risks (skin burns/irritation, contraindications, and misuse hazards). Second, it counsels against waiver language that overpromises “wellness only / no regulation,” because classification depends on actual claims and technology. ¹²

Where an electrotherapy device can land under FDA device classification

If claims or intended use cross into treatment territory, common regulatory anchors include:

- **TENS “for pain relief”** is a defined device type in FDA’s regulations (Class II) under 21 CFR § 882.5890. ¹³
- **Powered muscle stimulator** is defined under 21 CFR § 890.5850 (Class II) as an electrically powered device intended for medical purposes that repeatedly contracts muscles via electrodes. ¹⁴

FDA guidance for powered muscle stimulators also notes these are regarded as **prescription devices** and discusses the prescription-labeling framework (including reference to 21 CFR § 801.109). ¹⁵

Drafting implication: Your waiver and safety language should be consistent with the product’s intended use and should **not imply** diagnosis/treatment/clinical equivalence if you intend to remain in “general wellness.” FDA’s 2026 general wellness guidance expressly expects labeling and promotional materials to stay consistent with the stated intended use. ¹⁶

CPSC overlap for consumer products and why it matters in a “waiver” conversation

FDA notes that if a product is a “device” under the FD&C Act, it is generally excluded from the definition of “consumer product” under the Consumer Product Safety Act (with caveats about overlapping authorities). Waivers cannot contract around federal/state reporting or safety duties. ¹⁷

Enforceability landscape for consumer waivers in U.S. product sales

A waiver will not “erase product liability,” but it can reduce exposure if structured correctly

In U.S. practice, a harmed user can plead multiple overlapping theories: negligence, strict products liability, failure-to-warn, and breach of express/implied warranties. A “liability waiver” may help most with:

- **Assumption of risk** and “informed consent” (especially to known risks like skin irritation/burns), and
- **Warranty and remedy limitations** (to the extent permitted by UCC + Magnuson–Moss + state anti-disclaimer rules). ¹⁸

But there are hard limits:

- Many states refuse to enforce clauses that attempt to waive liability for **fraud, willful injury, or statutory violations** (e.g., California Civil Code § 1668). ¹⁹
- Courts may strike or narrow clauses that are **unconscionable** (UCC § 2-302) or that limit damages for **personal injury in consumer goods** in ways deemed prima facie unconscionable (UCC § 2-719(3)). ²⁰

Strict products liability is often resistant to “disclaimer by contract” in consumer settings

A core reason strict products liability exists is that it is **not supposed to depend on contract privity or contract disclaimers**. An Oregon appellate decision discussing § 402A comment m (and codified comments) quotes the classic point: the consumer’s cause of action “is not affected by any disclaimer or other agreement,” including those “attached to and accompanying the product.” ²¹

That same discussion (and Restatement (Second) Contracts § 195(3) as quoted there) frames an important nuance: disclaimers or liability waivers targeting strict products liability may be unenforceable as a matter of public policy except in “rare” fairly negotiated merchant-to-merchant contexts, and **they do not bind non-parties**. For ecommerce consumer sales, you should treat “strict liability waiver” language as **high-risk and often non-enforceable**, and instead focus on (a) informed assumption of risk, (b) warnings/IFU, (c) warranty structure, and (d) defensible remedy limitations. ²²

Warranty and remedy limitations: the high-leverage area—but heavily regulated

UCC baseline (most states, but with many consumer overrides).

- To disclaim implied warranty of merchantability, the disclaimer must mention “merchantability” and be conspicuous; implied warranty of fitness must be in writing and conspicuous. ²³
- Consequential damages can be limited or excluded unless unconscionable; limitation of consequential damages for **personal injury in consumer goods is prima facie unconscionable**. ²⁴

Magnuson–Moss (federal).

If you provide a **written warranty** or enter a **service contract** within 90 days, you generally cannot disclaim implied warranties (but you may be able to limit their duration to the duration of the written warranty, subject to state law). ²⁵

Magnuson–Moss also supports pre-sale availability of warranty terms, including in online sales channels.

²⁶

State “anti-disclaimer” statutes.

Several states sharply limit or prohibit disclaiming implied warranties in consumer sales, regardless of classic UCC phrasing (examples below). This is why your waiver must include “to the extent permitted by law” savings language and state-law carveouts, and why your operational plan should anticipate a “strict states” compliance posture rather than a one-size-fits-all disclaimer. ²⁷

Online assent is won or lost on “reasonable notice” + affirmative manifestation

Courts consistently focus on whether the user had **reasonably conspicuous notice** and **unambiguous assent**. Clickwrap-style processes (checkbox + clear statement that clicking/ordering means agreement + accessible terms) are repeatedly more enforceable than passive browsewrap. ²⁸

For post-purchase terms (inside the box), outcomes vary by jurisdiction and facts. Compare enforcement-friendly shrinkwrap reasoning (e.g., ProCD) with decisions that reject “box-stuffer” terms absent clear assent or where UCC formation analysis points the other way (e.g., Klocek). For consumer risk waivers, this strongly supports presenting the waiver **before payment** and again at **device activation** for end users. ²⁹

Electronic contracting validity is supported by the federal E-SIGN Act, which prevents denial of enforceability solely because the record/signature is electronic (subject to statutory exceptions and proper consumer consent frameworks where required). ³⁰

Recommended online presentation, acceptance methods, and recordkeeping

Presentation approach that best fits this risk profile

Because the product is an electrical-stimulation device (heightened injury plausibility), the best enforceability posture is **layered assent**:

Layer one: Checkout clickwrap (purchaser).

A required, unchecked checkbox directly above “Place Order,” stating: “By placing this order, I acknowledge I

have read and agree to the WellnessBox Product Liability Waiver & Release, and the Terms of Sale.” This aligns with the “reasonable notice + affirmative assent” posture courts have approved. ²⁸

Layer two: Activation clickwrap (end user).

Because gift recipients and household users may never see the checkout page, require each end user to accept the waiver during onboarding (QR code in the packaging → mobile page → acceptance stored). This also addresses the “non-party not bound” problem. ³¹

Layer three: Safety “key terms” screen (salient risks).

On both checkout and activation, show a short “Key Safety & Legal Terms” panel that highlights: contraindications (implanted devices), do-not-use zones (neck/carotid, transthoracic), burns/irritation risk, not for emergencies, limitation-of-liability cap (if any), and warranty baseline. Courts often react poorly to “buried” risk transfer; summarizing salient terms reduces procedural unconscionability arguments. ³²

Recordkeeping that maximizes evidentiary value

Maintain a **tamper-evident acceptance record** per purchaser and per end user:

- **Versioned agreement:** unique ID (e.g., WB-WAIVER-v1.3), with a PDF snapshot and SHA-256 hash stored at the time shown to the user.
- **Event log:** timestamp (UTC), user’s local time, IP address, user agent, checkout/order ID, and whether the user opened the full terms (if you present as modal/scroll).
- **Presentation proof:** the exact HTML text served (or a rendered PDF) stored with the same version ID.
- **Email receipt:** send the waiver text (or link plus version ID) in the order confirmation email (not as a substitute for clickwrap—just reinforcement). ³³

This structure is designed to defeat classic defenses: “I never saw it,” “the link was hidden,” “terms changed later,” or “I’m the user but not the buyer.” ³⁴

Recommended visual for internal implementation

Create a **one-page flowchart** (for engineering + legal sign-off) with nodes:

1) Product page → 2) Checkout page (checkbox + key terms) → 3) Payment → 4) Order confirmation email (version ID) → 5) Shipment insert (QR) → 6) Activation page (end-user clickwrap) → 7) Log/ledger storage → 8) Support workflow (injury complaint triggers “preserve evidence” + safety reporting decision tree).

This “systems view” is valuable because enforceability failures are usually process failures, not clause failures. ³⁵

Jurisdictional considerations and where enforceability commonly breaks

Key U.S. federal laws that shape claims and enforceability

- **FD&C Act device definition:** a “device” includes instruments intended to diagnose/treat disease or to affect structure/function (without chemical action). This interacts with how you describe WellnessBox in marketing and labeling, and whether you can credibly call it “general wellness.” ³⁶
- **FTC Act Section 5** (unfair or deceptive acts or practices): overstatement of health benefits, “FDA approved” misstatements, or hidden material limitations can trigger enforcement and private “mini-FTC” state claims. ³⁷
- **Magnuson–Moss Warranty Act:** constrains implied-warranty disclaimers if a written warranty/service contract is offered; also supports pre-sale availability of warranty terms. ³⁸
- **E-SIGN Act:** supports enforceability of electronic contracts/signatures, providing a legal backbone for clickwrap assent records. ³⁰

States with stricter consumer warranty / waiver rules to flag early

The table below focuses on **doctrinal choke points** that frequently undermine broad warranty disclaimers or “liability caps” in consumer physical-product sales.

Jurisdiction	“Why it’s stricter” (high-level)	Key authority
<code>["state", "California", "us state"]</code>	Public-policy limits on contracting away liability for fraud/willful injury/violation of law; strong consumer warranty regime; implied warranties often hard to waive except tightly controlled “as is” frameworks. ³⁹	
<code>["state", "Massachusetts", "us state"]</code>	Statute makes attempts to exclude/modify implied warranties in consumer goods/services unenforceable; also strong UDAP regime. ⁴⁰	
<code>["state", "Maine", "us state"]</code>	Statute provides that attempts to exclude/modify implied warranties in consumer goods/services are unenforceable (consumer override of classic UCC disclaimer rules). ⁴¹	
<code>["state", "Vermont", "us state"]</code>	Similar consumer override: implied warranties cannot be disclaimed for new/unused consumer goods/services. ⁴²	
<code>["state", "Maryland", "us state"]</code>	“2-316.1” consumer protection overlay restricting exclusion/modification of implied warranties in consumer transactions. ⁴³	

Jurisdiction	“Why it’s stricter” (high-level)	Key authority
Entity["place", "District of Columbia", "federal district us"]	Statutory “2-316.01” style consumer overlay making implied-warranty exclusions generally unenforceable (with limited “particular defects” exception). 44	
Entity["state", "Kansas", "us state"]	Consumer protection statute limits warranty disclaimers; allows limitation only for known defects and bars limitation for personal injury/property damage. 45	
Entity["state", "Mississippi", "us state"]	Consumer overlay restricting attempts to exclude/modify implied warranties; also contains formality requirements in some contexts. 46	

Drafting implication: If you want one national waiver, you must include (a) “to the maximum extent permitted by applicable law,” (b) severability and reformation-style language, and (c) explicit carveouts for non-waivable rights. Otherwise, an overbroad clause risks being struck and—worse—coloring the document as an adhesion contract with unfair surprise. 47

Clause options for different risk tolerances

The table below gives **modular alternatives** you can swap into the draft. Choose based on how aggressive you want to be versus (a) consumer expectations, (b) state-law enforceability, and (c) your insurance posture.

Clause module	More consumer-friendly (lower enforcement risk)	Balanced	More protective (higher enforcement challenge)
Limitation of liability cap	Cap for contract/warranty claims only (repair/replace/refund), and expressly no cap for personal injury where prohibited by law. 48	Cap “direct damages” to purchase price; keep carveouts for gross negligence/willful misconduct/statutory violations and nonwaivable consumer rights. 49	Cap “all claims” to purchase price and exclude consequential damages broadly— high risk in consumer injury cases (prima facie unconscionability and public policy). 49

Clause module	More consumer-friendly (lower enforcement risk)	Balanced	More protective (higher enforcement challenge)
Negligence release	Release only for ordinary negligence related to user misuse (e.g., ignoring contraindications) and preserve claims for product defects.	Release for ordinary negligence with conspicuous “INCLUDING NEGLIGENCE” language; preserve gross negligence/willful misconduct carveouts. ⁵⁰	Broad release of “any and all claims” including negligence—more likely to be challenged as overbroad/against public interest depending on state and context. ⁵⁰
Strict products liability waiver	Do not attempt; instead use assumption-of-risk + warnings + compliance posture. ²¹	If included, phrase as “to the extent permitted” acknowledgement; do not rely on it as primary protection. ²¹	“User waives strict liability” language—often ineffective in consumer settings and may backfire. ²¹
Indemnification (user → seller)	Indemnity limited to third-party claims caused by user’s misuse or unlawful conduct; no indemnity for seller’s own negligence/defects.	Indemnity for misuse + unauthorized modifications + using electrodes on prohibited areas.	Broad indemnity for “any claim related to use”—may be attacked as unconscionable in consumer setting. ²⁰
Gift recipient handling	Require end-user activation acceptance; otherwise warranty limited to purchaser; no waiver claimed against non-assenting third parties. ⁵¹	Same + purchaser covenant to provide safety info.	“Purchaser binds all users” language—often weak against non-parties. ²¹
Arbitration / class waiver (optional)	Omit; or offer opt-out and simple consumer-cost structure.	Include with clear notice and opt-out; keep fees reasonable; avoid one-sided venue/cost burdens. ⁵²	Hard-mandatory arbitration with costly forum/fees—risk of unconscionability challenges. ⁵³

Implementation checklist for enforceability and compliance

Workstream	Critical step	Evidence / artifact to retain
Legal	Confirm governing law + venue; decide risk tier options and “strict states” approach	Signed internal legal memo; waiver version matrix

Workstream	Critical step	Evidence / artifact to retain
Legal + CX	Align waiver with warranty/returns to avoid contradictions	Warranty PDF and checkout disclosures available pre-sale ⁵⁴
Engineering	Implement checkout clickwrap (unchecked box, forced assent, link opens waiver)	UI screenshots + HTML snapshot by version; event logs ⁵⁵
Engineering	Implement activation assent for end users (QR onboarding)	End-user acceptance ledger; version ID; device serial mapping
Product safety	Contraindications list + warnings consistent with intended use; avoid "treatment" claims unless you are ready for device compliance	IFU/manual; marketing claims review records ⁵⁶
Operations	"Litigation hold" process for injury reports; preserve logs and the exact version assented to	Incident ticket template; evidence preservation SOP
Compliance	Advertising substantiation and no "FDA-approved/cleared" claims unless true	Claims substantiation file; review checklist ⁵⁷
Data governance	Store assent logs with access controls; document retention schedule	Retention policy; audit trail (privacy-law overlay depends on states)

Draft waiver and release tailored to an electrotherapy device

The drafts below include **(A) Plain-English** and **(B) Legalese**. Both are written as a **standalone agreement** that can be linked at checkout and presented at activation. Bracketed fields are placeholders to fill once you provide missing inputs.

Plain-English draft

WELLNESSBOX ELECTROTHERAPY DEVICE - WAIVER, RELEASE, AND SAFETY AGREEMENT (PLAIN ENGLISH)

Version: [WB-WAIVER-vX.Y] • Effective: [DATE] • Governing law: [STATE] • Seller: WellnessBox, an unincorporated association ("WellnessBox," "we," "us")

Read this carefully. This agreement affects legal rights. If you do not agree, do not buy, use, or allow others to use the device.

Who this covers.

This agreement applies to: (1) the purchaser, (2) each person who uses the device, and (3) any person who helps set up or apply the device ("you").

What the product is (and is not).

WellnessBox is an electrical stimulation device intended for general wellness/training-type use as described in the instructions. It is not emergency care and is not a substitute for medical diagnosis or treatment. If you think you have a medical emergency, call 911 (or your local emergency number). ⁵⁸

Medical and safety warnings (do not use if any apply).

Do **not** use the device, and do not allow anyone else to use it, if any of these apply unless a licensed clinician has told you it is safe:

- You have a pacemaker, implanted defibrillator, deep brain stimulator, or other implanted electronic/metal medical device.
- You are pregnant or think you may be pregnant.
- You have epilepsy/seizure disorder, serious heart problems, or a condition where electrical stimulation could be unsafe.
- You have broken skin, severe skin irritation, or infection at the electrode site.

Stop use immediately if you experience burning, dizziness, fainting, chest pain, shortness of breath, abnormal heart rhythm sensation, or severe pain. Seek medical care if needed. ⁵⁹

Where you must NOT place electrodes.

Never place electrodes:

- On the front of the neck or across the throat (carotid sinus area).
- Across the chest/heart (transthoracic).
- On the head/face unless explicitly instructed by the official WellnessBox instructions.
- On genitals or over broken/inflamed skin.

Misuse increases the risk of serious injury. ⁶⁰

Known and possible risks you accept.

Electrical stimulation can cause risks including, for example: skin irritation, redness, discomfort, muscle soreness, and in some cases burns under the electrodes. Misuse—incorrect placement, too high intensity, prolonged sessions, use with contraindicated conditions, or altered devices—can increase risks. ⁶⁰

Assumption of risk.

You understand and voluntarily accept all known and unknown risks of using the device, including risks from electrical stimulation, electrode placement, intensity settings, and your own health condition.

Your responsibilities.

You agree to:

- Read and follow all instructions and warnings before each use.
- Use only WellnessBox-approved accessories/electrodes.
- Stop use if you feel burning, pain, dizziness, or abnormal symptoms.
- Keep the device away from children and never allow unsupervised use.
- Not use the device while sleeping, driving, bathing, or near water.

Release (waiver) of claims.

To the maximum extent allowed by law, you release WellnessBox from claims that result from:

- Your misuse, failure to follow instructions, or use despite contraindications;
- Your unauthorized modifications or use of non-approved accessories;
- Your decision to continue using the device after warning signs.

This release does **not** apply where the law does not allow it (for example, fraud, willful injury, or other nonwaivable duties). ⁶¹

Warranty disclaimer (important).

Except for any written limited warranty we provide in writing, **THE PRODUCT IS PROVIDED “AS IS” AND “AS AVAILABLE.” TO THE MAXIMUM EXTENT PERMITTED BY LAW, WE DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING THE IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.** ⁶²

If we provide a written warranty, implied warranties may be limited to the duration of that written warranty only where allowed by law. ²⁵

Limitation of liability.

To the maximum extent permitted by law:

- WellnessBox will not be liable for indirect, incidental, special, or consequential damages.
- If WellnessBox is found liable for any claim, our total liability will not exceed the amount you paid for the device (or [CAP AMOUNT]).

Some states do not allow certain limits, especially for personal injury in consumer goods, so these limits may not apply to you. ⁶³

Indemnification (third-party claims).

If your misuse, unauthorized modification, or unlawful use of the product causes a third party to sue WellnessBox, you agree to defend and reimburse WellnessBox for covered losses to the extent permitted by law.

Gifts and other users.

If you buy this product for someone else, you agree to give them the instructions and require them to accept this agreement before use. You understand that each user must accept this agreement at activation or before first use for it to apply to them. ⁶⁴

Minors.

You must be at least 18 to purchase. If you allow a minor to use the device, you accept full responsibility for supervision and safety. This agreement is intended to be accepted by an adult; minors may have special legal rights that cannot be waived.

Governing law and venue.

This agreement is governed by the laws of [STATE], and any permitted court action will be brought in [COUNTY, STATE], unless applicable law requires otherwise.

Electronic acceptance.

By clicking “I agree,” placing an order, or using the device, you sign this agreement electronically. ⁶⁵

Severability.

If any part is not enforceable, the rest remains in effect, and the unenforceable portion will be limited to the minimum extent needed to make it enforceable. ²⁰

Legalese draft

WELLNESSBOX ELECTROTHERAPY DEVICE – PRODUCT LIABILITY WAIVER, RELEASE, ASSUMPTION OF RISK, WARRANTY DISCLAIMER, LIMITATION OF LIABILITY, AND INDEMNITY AGREEMENT (LEGAL FORM)

Version: [WB-WAIVER-vX.Y] • Effective Date: [DATE]

WellnessBox (an unincorporated association) (“Company”) and the undersigned purchaser and/or user (“Releasor”)

Recitals. Releasor desires to purchase, receive, access, or use the WellnessBox electrotherapy/electrical-stimulation product, including all components, electrodes, accessories, software, instructions, packaging, replacement parts, and related services (collectively, the “Product”).

Acknowledgment of intended use; no medical advice. Releasor acknowledges the Product is offered for general wellness/fitness/recovery use as described in Company’s labeling and instructions; is not intended for emergency use; and is not a substitute for professional medical advice, diagnosis, or treatment. Releasor agrees to seek qualified medical advice regarding any condition that may render electrical stimulation unsafe and to contact emergency services in case of suspected emergency. ⁶⁶

Contraindications; duty to follow warnings. Releasor represents and warrants that Releasor (and any person Releasor permits to use the Product) will comply with all warnings, contraindications, and instructions, including prohibitions on electrode placement and use conditions, and will cease use immediately upon adverse symptoms. ⁶⁰

Assumption of risk. Releasor expressly and voluntarily assumes all risks of any kind, known or unknown, foreseeable or unforeseeable, relating to or arising out of the acquisition, possession, storage, setup, charging/powering, application, or use of the Product, including without limitation risks of discomfort, skin irritation, burns beneath electrodes, muscle contraction injury, and injuries arising from improper placement, excessive intensity, prolonged use, unsafe environments (including water), contraindicated use, or user health conditions. ⁶⁰

Release and waiver. To the maximum extent permitted by applicable law, Releasor irrevocably releases and discharges Company and its members, managers, agents, suppliers, and contractors (collectively, “Released Parties”) from any and all claims, demands, causes of action, liabilities, damages, losses, costs, and expenses (including attorneys’ fees) of any kind, whether in contract, tort, statute, or equity, arising out of or relating to the Product, INCLUDING CLAIMS ALLEGING NEGLIGENCE, except to the extent such release is prohibited by law (including, without limitation, willful injury, fraud, or other nonwaivable statutory duties). ⁶⁷

Product defects; limits of contract-based risk transfer. Releasor acknowledges that certain claims—particularly strict products liability claims for physical harm—may not be waivable by contract in consumer contexts and that this Agreement shall be construed to apply only to the maximum extent permitted by applicable law. ²¹

Disclaimer of warranties. EXCEPT AS EXPRESSLY SET FORTH IN A SEPARATE WRITTEN LIMITED WARRANTY ISSUED BY COMPANY (IF ANY), COMPANY DISCLAIMS ALL WARRANTIES TO THE MAXIMUM EXTENT PERMITTED BY LAW, WHETHER EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. Releasor

acknowledges that if Company provides a written warranty or enters a service contract subject to applicable law, implied warranty disclaimers may be restricted and implied warranties may be limited in duration only as permitted by law. ⁶⁸

Limitation of liability. TO THE MAXIMUM EXTENT PERMITTED BY LAW: (a) IN NO EVENT SHALL ANY RELEASED PARTY BE LIABLE FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, EXEMPLARY, OR PUNITIVE DAMAGES; (b) COMPANY'S TOTAL AGGREGATE LIABILITY FOR ANY AND ALL CLAIMS SHALL NOT EXCEED THE PURCHASE PRICE PAID FOR THE PRODUCT (OR [CAP AMOUNT]), PROVIDED THAT LIMITATIONS ON DAMAGES FOR PERSONAL INJURY IN CONNECTION WITH CONSUMER GOODS MAY BE RESTRICTED OR DEEMED UNCONSCIONABLE UNDER APPLICABLE LAW. ⁶³

Indemnification (third-party claims). To the maximum extent permitted by law, Releasor shall indemnify, defend, and hold harmless the Released Parties from and against any third-party claims and resulting losses arising out of or related to (i) Releasor's misuse of the Product, (ii) Releasor's unauthorized modification, (iii) use with non-approved accessories, (iv) violation of instructions/warnings, or (v) unlawful or reckless conduct.

Gifts; additional users; non-parties. Releasor acknowledges that individuals who do not assent to this Agreement may not be bound; accordingly, Releasor agrees to require all end users to accept this Agreement prior to first use (e.g., activation clickwrap). Releasor further agrees to provide all safety warnings and instructions to any recipient or additional user. ⁶⁴

Minors. Releasor represents Releasor is at least 18 years of age (or the age of majority in Releasor's jurisdiction) to purchase. Any minor use is solely at the supervising adult's risk and responsibility, and nothing herein is intended to waive any minor's nonwaivable rights.

Governing law; venue. This Agreement shall be governed by the laws of [STATE], without regard to conflict-of-laws rules. Exclusive venue for any action not subject to mandatory statutory venue shall be [COUNTY, STATE], and the parties consent to personal jurisdiction there.

Electronic signature; acceptance. Releasor agrees that clicking acceptance, placing an order, using the Product, or otherwise indicating assent constitutes an electronic signature and acceptance of this Agreement. ⁶⁵

Severability; construction. If any term is held unenforceable, it shall be severed or reformed to the minimum extent necessary to be enforceable, and the remainder shall remain in full force and effect. ²⁰

Targeted alternative clauses you can swap in (copy/paste)

Alternative A (more enforceable; narrower negligence waiver).

"Releasor releases claims to the extent arising from Releasor's failure to follow written instructions/warnings, contraindicated use, or unauthorized modifications. This release does not apply to claims arising solely from a manufacturing defect independent of Releasor's misuse."

Alternative B (more consumer-friendly limitation of liability).

“Company’s liability for breach of any written warranty is limited to repair, replacement, or refund at Company’s option. Nothing in this Agreement limits liability that cannot be limited under applicable law.”

Alternative C (gift recipient activation condition precedent).

“Use of the Product is conditioned on end-user acceptance at activation. If the end user does not accept, the Product must not be used and may be returned under the return policy.”

Each alternative is designed to reduce “overbreadth” and procedural/substantive unconscionability arguments while still emphasizing assumption of risk and misuse-based defenses. ⁶⁹

Selected primary sources used in this report

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>
<https://www.fda.gov/media/90652/download>
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-882/subpart-F/section-882.5890>
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-890/subpart-F/section-890.5850>
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-D/section-801.109>
<https://www.law.cornell.edu/uscode/text/21/321>
https://www.law.cornell.edu/definitions/uscode.php?def_id=21-USC-1335157162-263717922
<https://www.law.cornell.edu/uscode/text/15/2308>
<https://www.law.cornell.edu/ucc/2/2-316>
<https://www.law.cornell.edu/ucc/2/2-719>
<https://www.law.cornell.edu/uscode/text/15/7001>
<https://law.justia.com/cases/federal/appellate-courts/ca2/16-2750/16-2750-2017-08-17.html>
<https://cdn.ca9.uscourts.gov/datastore/opinions/2014/08/18/12-56628.pdf>
<https://law.justia.com/cases/federal/appellate-courts/F3/86/1447/538242/>
<https://law.justia.com/cases/federal/district-courts/FSupp2/104/1332/2503865/>

¹ ³⁰ ⁶⁵ <https://uscode.house.gov/view.xhtml?edition=prelim&path=%2Fprelim%40title15%2Fchapter96>
<https://uscode.house.gov/view.xhtml?edition=prelim&path=%2Fprelim%40title15%2Fchapter96>

² ⁶ ²⁸ ³³ ³⁵ ⁵⁵ <https://law.justia.com/cases/federal/appellate-courts/ca2/16-2750/16-2750-2017-08-17.html>
<https://law.justia.com/cases/federal/appellate-courts/ca2/16-2750/16-2750-2017-08-17.html>

³ ¹⁰ **Wellness Box: Home**
https://getwellnessbox.com/?utm_source=chatgpt.com

- 4 20 32 47 52 53 69 <https://www.law.cornell.edu/ucc/2/2-302>
<https://www.law.cornell.edu/ucc/2/2-302>
- 5 27 40 **Part I, Title XV, Chapter 106, Article2, Section 2-316A**
https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXV/Chapter106/Article2/Section2-316A?utm_source=chatgpt.com
- 7 25 38 **15 U.S. Code § 2308 - Implied warranties - Cornell Law School**
https://www.law.cornell.edu/uscode/text/15/2308?utm_source=chatgpt.com
- 8 13 **21 CFR 882.5890 -- Transcutaneous electrical nerve ...**
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-882/subpart-F/section-882.5890?utm_source=chatgpt.com
- 9 **<https://www.churchlawandtax.com/pastor-church-law/organization-and-administration/unincorporated-associations/characteristics/>**
<https://www.churchlawandtax.com/pastor-church-law/organization-and-administration/unincorporated-associations/characteristics/>
- 11 12 16 56 58 **<https://www.fda.gov/media/90652/download>**
<https://www.fda.gov/media/90652/download>
- 14 **21 CFR 890.5850 -- Powered muscle stimulator.**
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-890/subpart-F/section-890.5850?utm_source=chatgpt.com
- 15 59 60 **Guidance Document for Powered Muscle Stimulator 510(k)s**
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-document-powered-muscle-stimulator-510ks-guidance-industry-fda-reviewersstaff-and?utm_source=chatgpt.com
- 17 **<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>**
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices>
- 18 23 62 68 **2-316. Exclusion or Modification of Warranties.**
https://www.law.cornell.edu/ucc/2/2-316?utm_source=chatgpt.com
- 19 39 61 67 **Section 1668. - 2025 California Code :: Civil Code**
https://law.justia.com/codes/california/code-civ/division-3/part-2/title-4/section-1668/?utm_source=chatgpt.com
- 21 22 31 64 **<https://law.justia.com/cases/oregon/court-of-appeals/1993/122-or-app-508.html>**
<https://law.justia.com/cases/oregon/court-of-appeals/1993/122-or-app-508.html>
- 24 48 49 63 **2-719. Contractual Modification or Limitation of Remedy.**
https://www.law.cornell.edu/ucc/2/2-719?utm_source=chatgpt.com
- 26 54 **2302**
https://www.govinfo.gov/link/uscode/15/2302?utm_source=chatgpt.com
- 29 **<https://law.justia.com/cases/federal/appellate-courts/F3/86/1447/538242/>**
<https://law.justia.com/cases/federal/appellate-courts/F3/86/1447/538242/>
- 34 51 **<https://law.justia.com/cases/federal/appellate-courts/ca9/12-56628/12-56628-2014-08-18.html>**
<https://law.justia.com/cases/federal/appellate-courts/ca9/12-56628/12-56628-2014-08-18.html>
- 36 66 **https://www.law.cornell.edu/definitions/uscode.php?def_id=21-USC-1335157162-263717922**
https://www.law.cornell.edu/definitions/uscode.php?def_id=21-USC-1335157162-263717922
- 37 57 **<https://www.law.cornell.edu/uscode/text/15/45>**
<https://www.law.cornell.edu/uscode/text/15/45>

41 <https://legislature.maine.gov/statutes/11/title11sec2-316.html>

<https://legislature.maine.gov/statutes/11/title11sec2-316.html>

42 <https://legislature.vermont.gov/statutes/section/09a/002/00002>

<https://legislature.vermont.gov/statutes/section/09a/002/00002>

43 <https://law.justia.com/codes/maryland/commercial-law/title-2/subtitle-3/section-2-316-1/>

<https://law.justia.com/codes/maryland/commercial-law/title-2/subtitle-3/section-2-316-1/>

44 <https://code.dccouncil.gov/us/dc/council/code/sections/28%3A2-316.01>

<https://code.dccouncil.gov/us/dc/council/code/sections/28%3A2-316.01>

45 <https://law.justia.com/codes/kansas/chapter-50/article-6/section-50-639/>

<https://law.justia.com/codes/kansas/chapter-50/article-6/section-50-639/>

46 <https://law.justia.com/codes/mississippi/title-75/chapter-2/part-3/section-75-2-316/>

<https://law.justia.com/codes/mississippi/title-75/chapter-2/part-3/section-75-2-316/>

50 <https://law.justia.com/cases/california/supreme-court/2d/60/92.html>

<https://law.justia.com/cases/california/supreme-court/2d/60/92.html>